

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO:</b>  <b>ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' NOTICE OF ADOPTION OF WAVE 1 MOTION</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS'  
MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY  
OF CHRISTINA PRAMUDJI, M.D.**

**INTRODUCTION**

Plaintiffs filed a Notice of Adoption of their Motion to Exclude Certain Opinions and Testimony of Christina Pramudji, M.D. [Doc. No. 2035] and Supporting Memorandum [Doc. No. 2037] from Ethicon Wave 1. *See* Plaintiffs' Notice of Adoption, Doc. No. 2427. While Ethicon adopts and incorporates by reference its Response to that Motion ("Ethicon's Response") [Doc. No. 2153], given recent testimony from Dr. Pramudji and her updated Reports and reliance lists for Wave 2 cases, there is additional, relevant information to consider in addressing Dr. Pramudji's opinions on product warnings and that polypropylene mesh does not degrade in vivo.

Other than the supplementation of these two issues, Ethicon adopts and incorporates herein by reference its Wave 1 Response in relation to Dr. Pramudji [Doc. No. 2153].

## BACKGROUND

Dr. Pramudji is a board-certified urologist with a sub-specialty in Pelvic Floor Medicine and Reconstructive Surgery. Ethicon’s Response [Doc. No. 2153] at 1.<sup>1</sup> Her experience is vast, including “well over 1000” prolapse surgeries; “over 900 sling procedures” to treat SUI; 10 to 20 complete explants; and 50-60 revisions or partial removals. *Id.* She has also taught many surgeons on the use of mesh devices, has consulted with medical device companies in the development of slings to treat SUI, and has closely studied the medical literature and studies related to mesh, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. *Id.* at 1-2.

Plaintiffs seek to preclude Dr. Pramudji from testifying about the adequacy of the device IFUs, arguing that she is not an expert on regulations governing device manufacturers and is instead relying solely on her experience as a surgeon. And Plaintiffs attempt to preclude Dr. Pramudji from offering testimony that polypropylene mesh products do not degrade in the human body. None of Plaintiffs’ arguments has merit, and their Motion should be denied.

**A. Dr. Pramudji is qualified to testify about the general knowledge of pelvic floor surgeons and the impact of such knowledge on Ethicon’s Warnings and IFUs.**

“[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings.” *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at \*5 (S.D. W. Va. Apr. 24, 2015). Dr. Pramudji’s testimony should be considered in light of the controlling legal principle that a device manufacturer’s duty to warn of adverse events does not include a

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<sup>1</sup> Ethicon will not restate the entirety of Dr. Pramudji’s qualifications here, but refers the Court to its Response, Doc. No. 2153, at 1-2.

duty to warn of risks commonly known to the surgeons who use the device. Even the FDA device regulations recognize the importance of a physician's knowledge base by allowing certain information to be omitted from labeling:

if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known to practitioners* licensed by law to use the device.

21 C.F.R. §801.109(c) (emphasis added).

As a result, Dr. Pramudji's testimony concerning what a trained pelvic floor surgeon would know to be the risks associated with pelvic floor surgeries, including surgery using mesh, is a key inquiry here, and she is undoubtedly qualified to render opinions on this topic. So, too, Dr. Pramudji's analysis of the pertinent medical literature supports her conclusions that numerous risks attendant to performing the surgery and using the device would be commonly known to these practitioners (surgeons like herself) licensed to implant the device and that certain risks espoused by Plaintiffs' experts are unverified and therefore need not be included in the IFU. *See, infra*, regarding Dr. Pramudji's opinions on degradation.

This makes sense in light of the fact that the contents of the IFUs must be assessed in terms of both what the class of surgeons who are to use the devices know and how their training would impact their review of the IFUs. *See, e.g.*, Ex. C to Ethicon's Response, TVT IFU at 28 ("Users should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system." And, that the IFU "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)."); Ex. D to Response, TVT-O IFU at 5 (device to be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device."); Ex. A, Prolift IFU at 2 ("Training on the use of the GYNECARE

PROLIFT\* Pelvic Floor Repair Systems is recommended and available”) and at 6 (“WARNINGS AND PRECAUTIONS: Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.”)).

Dr. Pramudji has recently expounded on her experience in training other physicians in the use of mesh devices, including evaluating the risks to determine appropriate patients and how her experience as a pelvic surgeon plays into that. For example, in *Shelton v. Ethicon, Inc.*, No. 2:12-cv-01707, upon questioning by Plaintiff’s counsel, Dr. Pramudji testified that she taught other physicians about Ethicon mesh products, how to implant them, and how to identify a proper patient for treatment using mesh. Ex. B, Pramudji (*Shelton* 7/12/16) Dep. at 54-55. She highlighted that her experience and professional education, in combination with reading medical literature over her decades of practice, has informed her opinion regarding the risks and complications of pelvic floor surgery and pelvic floor surgery using mesh. *Id.* at 68-70. And she also testified that she knows what risks and complications are known to pelvic surgeons, the intended product users, not only through her experience, but also through a thorough review of the literature over many years. *Id.* at 68-70 (citing Iglesia, C.B., *The Use of Mesh in Gynecologic Surgery*, Int. Urogynecol J (1997) 8:105-115, which was a literature review from 1950 to 1997 published in the International Urogynecology Journal, that reported risks to practitioners like Dr. Pramudji).

Dr. Pramudji edified her opinions concerning the knowledge base of pelvic surgeons and what pelvic surgeons fundamentally and commonly know based upon experience in that surgical field. “A fundamental part of training to pelvic floor surgeons” is that surgery in the pelvic area can cause certain complications that are customarily raised by Plaintiffs in this litigation,

including scarring in the vagina and inflammation in the vaginal wall, which can result in dyspareunia. Ex. C, Pramudji (*Bihlmeyer v. Ethicon, Inc.*, No. 2:12-cv-02159) (6/9/16) Dep. at 95. She explained that medical studies dating back to 1961 tracked the connection between pelvic floor surgery and dyspareunia. *Id.* at 95-96. For more than 50 years, pelvic surgeons in the field have understood the well-accepted risks of pelvic floor surgery to include scarring and tenderness, potential narrowing of the introitus and vagina and dyspareunia. *Id.* at 96. This is consistent with her General Expert Reports. *See*, Ex. C to Plaintiff's Motion [Doc. No. 2035], Pramudji Gynemesh/Prolift/Prosima General Report, at 16 ("Pain, pelvic pain and dyspareunia can occur with all POP surgeries.") (citing ACOG 2011 Committee Opinion 513; AUA 2011 Position Statement on the use of vaginal mesh for the repair of pelvic organ prolapse; Lowman, J., *Does the Prolift system cause dyspareunia?* Am J Obstet Gynecol 2008, 199:707.e1-707.e6; Francis, WJA, Jeffcoate, TNA, *Dyspareunia following vaginal operations*, J Obstet Gynaecol Br Commonwealth, 1961, LXVIII(1):1-10 (discussing complications following colporrhaphy prolapse repair)); and at 15 ("All POP and vaginal surgeries have potential risks.") (citing Ex. D, Diwadkar, *Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review*, Obstet Gynecol 2009, 113:367-73 (published in the official publication of the American College of Obstetricians and Gynecologists, and reviewing literature from 1985 to January 2008 using PubMed, Cochrane databases, and the Database of Abstracts of Reviews and Effects and reporting numerous risks and complications to practitioners of pelvic floor surgery); *see also* Diwadkar, at Table 2:

**Table 2. Weighted Averages and Confidence Intervals of Complications, Dindo Grades, Prolapse Reoperation Rates, and Total Reoperation Rates**

	Traditional Vaginal Repair*	Sacral Colpopexy	Mesh Kits
Number of studies <sup>†</sup>	48	52	24
Number of patients	7,827	5,639	3,425
Mean follow-up (mo±SD)	32.6±19.8	26.5±20.1	17.1±13.8
Dindo grade I	6.2 (5.7–6.7), 0–52.8	5.5 (4.9–6.1), 0–52.2	3.9 (3.3–4.6), 0–23.1
Dindo grade II	6.9 (6.4–7.6), 0–34.7	5.8 (5.2–6.4), 0–25.9	2.2 (1.7–2.7), 0–14.8
Dindo grade IIIa	0.2 (0.1–0.4), 0–2.1	1.0 (0.7–1.2), 0–8.3	1.3 (0.9–1.6), 0–12.7
Dindo grade IIIb	1.9 (1.7–2.3), 0–12.0	4.8 (4.2–5.4), 0–28.2	7.2 (6.3–8.0), 0–21.2
Dindo grade IVa, b	0.1 (0–0.1), 0–1.0	0.0 (0–0.07), 0–0	0.0 (0–0.1), 0–0
Dindo grade V	0.1 (0–0.1), 0–0.7	0.0 (0–0.07), 0–0	0.0 (0–0.1), 0–0
Mesh erosion or infection	0.5 (0.3–0.6), 0–20.0	2.2 (1.8–2.6), 0–28.2	5.8 (5–6.6), 0–21.2
Visceral injury <sup>‡</sup>	1.0 (0.8–1.3), 0–5.9	1.7 (1.3–2.0), 0–10.7	1.1 (0.7–1.4), 0–5.0
Cystostomy	0.4 (0.2–0.5), 0–5.9	1.0 (0.8–1.3), 0–10.7	0.7 (0.4–1.0), 0–4.3
Ureteral injury	0.3 (0.2–0.4), 0–3.5	0.2 (0.1–0.3), 0–1.6	0.1 (0–0.1), 0–1.0
Bowel injury	0.4 (0.3–0.5), 0–3.1	0.5 (0.3–0.7), 0–3.6	0.3 (0.1–0.5), 0–5.0
Pain <sup>§</sup>	1.6 (1.3–1.9), 0–38.9	2.3 (1.9–2.6), 0–25.0	2.5 (2.0–3.0), 0–23.1
Buttock pain	1.0 (0.8–1.3), 0–52.8	0.0 (0–0.07), 0–5.9	0.4 (0.2–0.7), 0–8.3
Dyspareunia	1.5 (1.2–1.8), 0–38.9	1.5 (1.1–1.8), 0–22.8	2.2 (1.7–2.7), 0–23.1
Fistula	0.1 (0–0.1), 0–1.5	0.0 (0–0.07), 0–0.8	0.2 (0.1–0.4), 0–4.2
Hemorrhage or hematoma	2.8 (2.5–3.3), 0–19.6	1.6 (1.3–1.9), 0–11.5	1.1 (0.7–1.4), 0–3.0
Wound complications <sup>  </sup>	0.5 (0.4–0.7), 0–10.8	1.5 (1.2–1.8), 0–16.8	0.2 (0–0.3), 0–7.5
Pelvic abscess	0.2 (0.1–0.3), 0–1.4	0.1 (0–0.2), 0–3.2	0.1 (0–0.2), 0–3.3
Lower extremity neuropathy	0.4 (0.3–0.6), 0–7.5	0.2 (0.1–0.3), 0–0.5	0.0 (0–0.1), 0–0
Urinary tract infection	3.5 (3.1–3.9), 0–34.8	2.1 (1.8–2.5), 0–25.9	0.8 (0.5–1.2), 0–14.8
Pulmonary embolism or deep vein thrombosis	0.1 (0.1–0.2), 0–2.2	0.3 (0.1–0.4), 0–3.2	0.0 (0–0.1), 0–1.4
Pulmonary complications	0.5 (0.4–0.7), 0–14.0	0.1 (0.1–0.4), 0–0.7	0.0 (0–0.1), 0–0
Cardiac complications	0.2 (0.1–0.3), 0–2.2	0.2 (0.1–0.3), 0–3.3	0.0 (0–0.1), 0–0
Total complication rate	15.3 (14.7–16.3), 0–52.8	17.1 (16.1–18.1), 0–52.2	14.5 (13.3–15.7), 0–23.1
Reoperation for prolapse recurrence	3.9 (3.5–4.4), 0–29.1	2.3 (1.9–2.7), 0–31.3	1.3 (1.0–1.7), 0–16.0
Total reoperation rate <sup>§</sup>	5.8 (5.3–6.3), 0–29.2	7.1 (6.4–7.8), 0–26.2	8.5 (7.6–9.4), 0–30.0

SD, standard deviation.

Data are % (95% confidence interval), range unless otherwise specified.

\* Includes sacrospinous ligament suspension, uterosacral ligament suspension, ilioococcygeus muscle suspension, and McCall's culdoplasty.

† Ten studies included multiple cohorts from different procedure groups.

‡ Includes cystostomy, ureteral injury, and bowel injury.

§ Includes buttock pain, dyspareunia, and unspecified pain.

|| Includes wound infections, vaginal cuff infections, and vaginal and abdominal wound dehiscences.

§ Includes reoperations for complications (Dindo IIIb) and prolapse recurrence.

See also Ex. B to Plaintiffs' Motion [Doc. 2035], Pramudji TVT/TVTO General Report at 4 (“Potential risks of operating in this area are well described to surgeons during training, in medical textbooks, and in the medical literature, and are well known risks” and generally discussing risks set forth in the medical literature).

All of this supports her qualifications to testify about the general knowledge of pelvic floor surgeons and why, given that general knowledge base, warnings that Plaintiffs insist should have been included in the product warnings were simply not necessary in light of the knowledge of the intended user of the product.

In addition, Dr. Pramudji's experience qualifies her to testify concerning the common interpretation of the risks set forth in the IFU to those trained in such surgeries. See, e.g., Ex. E, Pramudji (*Wilson v. Ethicon, Inc.*, No. 2:12-cv-02099) (7/6/16) Dep. at 77-83 (discussing that risks known to pelvic surgeons would impact the surgeon's interpretation of the language in the product warnings).

Given that the product IFUs note that only surgeons trained in pelvic floor surgery should use Ethicon pelvic mesh products, Defendants’ Response Memorandum [Doc. No. 2153] at 5-6, what a trained physician would know is critical to the analysis of the adequacy of the warning. Dr. Pramudji is well-versed by her education, training and experience – including her experience training other surgeons – to discuss what risks would be known generally to the class of users of such mesh devices. She is further qualified by her work as a preceptor and Ethicon trainer to discuss what training Ethicon provided, including the format of the training as well as its content. Ex. C, Pramudji (*Bihlmeyer*) Dep. at 96-98; Ex. B, Pramudji (*Shelton*) Dep. at 54-56.

Dr. Pramudji is not opining that certain risks need not be included in the IFU just because she has not observed them in her own practice. Instead, her testimony rests not only her own experience but on her historical review of the medical literature as well as her experience in teaching medical professionals and the statement of the professionals themselves through their professional associations. Such opinions are fully supported by her years of education, training and experience: qualifications that Plaintiffs do not challenge. *See* Plaintiffs’ Reply Memorandum in Support of Motion to Exclude Certain Opinions of Christina Pramudji, M.D. [Doc. No. 2236] at 1 (“Plaintiffs’ Motion is not based on lack of qualifications...”). Yet qualifications are at the heart of Dr. Pramudji’s opinion that, given the knowledge of pelvic floor surgeons, the product warnings were adequate.

This Court’s rulings in *Tyree* and *Bellew* are distinguishable. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D. W. Va. 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (Daubert Motions), Doc. 265 at 33 (S.D. W. Va. Nov. 20, 2014). While a single physician’s experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the

clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Pramudji has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. *Tyree*, 54 F. Supp. 3d at 561. In *Tyree*, Dr. Blaivas was permitted to testify as to whether any "inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the product was. *Id.* It stands to reason that an expert employing this same, or better, methodology, while reaching a different conclusion concerning the impact of a claimed omission on a trained surgeon, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Pramudji's conclusion can be addressed on cross-examination.

Plaintiffs argue that Dr. Pramudji does not support her opinion on what pelvic floor surgeons know with any specific study or research, which is a far too restrictive reading of *Daubert*. Plaintiffs' Reply in Further Support of their Motion to Exclude Certain Opinions and Testimony of Christina Pramudji, MD [Doc. No. 2236] at 2-4. Yet they have likewise failed to identify any study that challenges Dr. Pramudji's assessment of what risks or complications are so obvious or so common to pelvic floor surgery that any surgeon attempting to perform surgery should know it. Some risks and complications are just so well understood that there is no reason to conduct a study to quantify them. In fact, this Court recognized that expert opinion based on clinical practice is "obviously ... not subject to testing or peer-review." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 727 (S.D. W. Va. 2014). Nor does *Daubert* require such testing when an expert is relying upon her education, training and experience to form her opinions. *Id.* at 726. And Plaintiffs do not address the fact that Dr. Pramudji bases her opinions on her extensive review of the medical literature as set forth in her General Reports, which informs practitioners

who would use the device, as well as risks commonly taught in the training of the pelvic surgeon, which she is certainly qualified to give.

And just because some hypothetical physicians may overestimate their abilities to perform surgeries that they lack the training to perform does not render inadmissible generalizations about what someone who *is* qualified to perform such surgeries would know. *See* Plaintiffs’ Reply [Doc. No. 2236] at 3-4. Such generalizations are not only proper but expressly approved of by the FDA regulations applying to warnings. Those regulations provide that information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings and other information are **commonly known** to practitioners licensed by law to use the device.” 21 C.F.R. §801.109(c) (emphasis added). Thus, the regulations themselves contemplate that some generalization of knowledge of the intended users is properly considered. Other than through testimony from such intended users, it would not be possible to meet this standard.

Given the established relevance of the knowledge of pelvic floor surgeons generally, and given Dr. Pramudji’s unassailable education, training and experience as a pelvic floor surgeon, her extensive review of the medical literature which outlines risks that would inform the intended user, her review of the devices’ professional education materials and her teaching to and interaction with other intended users concerning risks and the IFU, her testimony regarding such general knowledge and how such general knowledge impacts the interpretation of the product warnings by the intended user is proper.

**B. Dr. Pramudji’s opinion that polypropylene mesh does not degrade in vivo is further supported by recent medical literature.**

This Court has previously ruled that Dr. Pramudji can testify about whether she has observed mesh degradation in her clinical practice. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691,

726 (S.D. W. Va. 2014). Such opinions are proper given her considerable experience and her review of mesh images received from pathologists. *Id.*

In *Huskey*, Ethicon agreed that Dr. Pramudji would not testify regarding the chemical process of degradation of polypropylene. The same holds true here. However, Dr. Pramudji is qualified to opine beyond just the fact that she has not seen degradation in her clinical practice. She can also testify that the medical literature does not support the conclusion that polypropylene mesh degrades in vivo. *See, e.g.*, Ex. F, Pramudji Supplemental Reliance list for Wave 2 (*Shelton*).

Dr. Pramudji has reviewed extensive medical literature on this subject and routinely keeps up to date on such literature. *See* General Reports, Exs. B and C to Plaintiffs’ Motion [Doc. No. 2035]; Reliance List, Ex. B to Ethicon’s Response [Doc. No. 2153]; *see, e.g.*, Ex. F, Supplemental Reliance List for Wave 2 (*Shelton*). For example, in her TVT General Report she outlines that “Degradation of the mesh has not been demonstrated by reliable data. While there have been reports of ‘surface cracking’ such as that described in the Clave 2010 paper, the authors there confirm that the phenomenon which was only observable in a minority of specimens could not be demonstrated on analytical chemical testing.” Ex. B to Plaintiffs’ Motion [Doc. No. 2035] at 62-63. “Moreover, the methodology of the paper was flawed and unable to rule out that the surface cracking was not biofilm. The data do not support that any surface cracking causes clinical symptoms.... Prospective studies have followed patients with implanted with TVT and TVT-O for 5-17 years and show excellent durability and safety with the use of the macroporous Prolene polypropylene sling. (citations omitted). Numerous data cited in my report show that the macroporous Prolene polypropylene tape is well tolerated and provides lasting efficacy for SUI.” *Id.* at 63-64. After citing a host of medical literature and studies analyzing

the lack of degradation, Dr. Pramujdi properly opines that “[t]hese data are inconsistent with Plaintiff’s experts’ theories.” *Id.* at 65. *See also* Ex. C to Plaintiffs’ Motion [Doc. No. 2035] at 3 (“The data in women does not support that Gynemesh PS degrades, as reoperation rates for recurrence are low, cure rates and satisfaction is high, and complication rates are not consistent with degradation or that if it did degrade, it would have a clinically significant effect”) and at 15-35, 40-46 (regarding the data which she has reviewed and which does not support Plaintiffs’ degradation theory). As she testified in a recent deposition:

Q. You were asked a question about whether all of the general materials in your prior general report are the entire scope of your general opinions.

Do you recall a question somewhat along those lines?

A. Yes.

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Q. Doctor: Have you, since the time of your most recent general Gynemesh Prolift report, continued to review the literature with regard to those products?

A. Yes.

Q. And have you, in prior depositions, noted the additional materials that you have reviewed that don’t change your opinion but are just further supportive of your opinions?

A. Yes.

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Q. [Such as] The paper to be presented at IUGA on the lack of support for a degradation theory showing that the correct material is instead a biologic proteinaceous material?

A. Yes.

Ex. B, Pramudji (7/12/16) Dep. (*Shelton*) at 61-62. As noted on Dr. Pramudji’s updated reliance list and referenced in her above testimony, she has reviewed and considered a recent study that

shows that the substance on mesh explants that Plaintiffs' experts claim is degrading polypropylene is instead a protein layer produced by the human body. Ex. F, Supplemental Reliance list for Wave 2 (*Shelton*) at 28 (citing Ex. G, Ong, Thames, et.al, *The Myth: In Vivo Degradation of Polypropylene Meshes*, Int Urogynecol J (2016) 27 (Suppl 1):S37-38). This study specifically examined the flaking particles on explanted mesh, including cracked and uncracked regions, through numerous methods and found that the meshes did not undergo degradation; instead the particles and cracked layer were actually an adsorbed protein layer, i.e., a natural and well-known reaction by the human body to the implantation of a foreign device. *Id.* This study fully supports Dr. Pramudji's testimony that in vivo degradation of polypropylene mesh is not established in either her clinical experience or in the medical literature. Since such literature is the kind of information relied upon by clinicians like Dr. Pramudji in their medical practice, she is qualified to offer an opinion that not only has she never seen degradation of polypropylene mesh in her personal experience, but that the medical literature does not support such a finding.

In *Huskey*, this Court permitted Dr. Harry Johnson to testify to just that. *Huskey*, 29 F. Supp. 3d at 733-34. The basis for his opinion was Dr. Johnson's clinical experience and review of medical literature on the subject. *Id.* So, too, Dr. Pramudji should be permitted to testify that medical literature does not support that polypropylene mesh degrades.

As in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at \*7 (S.D. W. Va. Apr. 28, 2016), Dr. Pramudji "considered and analyzed multiple scientific articles" and "drew on [her] clinical experience" to reach her opinion that polypropylene does not degrade. This Court found that this constitutes a "reliable, scientific methodology." *Id.* Thus, Dr. Pramudji is qualified to

opine on the lack of evidence that polypropylene degrades from both her clinical experience and from the medical literature, and her opinion meets *Daubert* criteria. *Id.*

### CONCLUSION

For the reasons set forth above, and all reasons set forth in Ethicon's Response to Plaintiffs' Motion to Exclude Certain Opinions of Dr. Pramudji [Doc. No. 2153], the Court should deny Plaintiffs' Motion.

This the 8<sup>th</sup> day of August, 2016.

Respectfully submitted,

ETHICON, INC. AND  
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### CERTIFICATE OF SERVICE

I certify that on August 8, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones  
Christy D. Jones

# EXHIBIT A

# Gynecare PROLIFT\*

Total Pelvic Floor Repair System  
Anterior Pelvic Floor Repair System  
Posterior Pelvic Floor Repair System

System til total reparation af bækkenbund  
System til anterior reparation af bækkenbund  
System til posterior reparation af bækkenbund

Systeem voor reparatie van de gehele bekkenbodem  
Systeem voor reparatie van de anterieure bekkenbodem  
Systeem voor reparatie van de posterieure bekkenbodem

Totaali lantionpohjan korjausjärjestelmä  
Anteriorinen lantionpohjan korjausjärjestelmä  
Posteriorinen lantionpohjan korjausjärjestelmä

Système pour cure de prolapsus total  
Système pour cure de prolapsus antérieur  
Système pour cure de prolapsus postérieur

Totalprolaps-Beckenboden-Rekonstruktionssystem  
Anteriores Beckenboden-Rekonstruktionssystem  
Posteriores Beckenboden-Rekonstruktionssystem

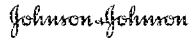
Sistema di riparazione totale del pavimento pelvico  
Sistema di riparazione anteriore del pavimento pelvico  
Sistema di riparazione posteriore del pavimento pelvico

Sistema de reparação do pavimento pélvico total  
Sistema de reparação do pavimento pélvico anterior  
Sistema de reparação do pavimento pélvico posterior

Sistema de reparación del suelo pélvico total  
Sistema de reparación del suelo pélvico anterior  
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten  
System för reparation av främre delen av bäckenbotten  
System för reparation av bakre delen av bäckenbotten

Σύστημα ολικής αποκατάστασης πυελικού εδάφους  
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους  
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

Manufactured for:  
GYNECARE WORLDWIDE  
A division of ETHICON, INC.  
a  company  
Somerville, New Jersey 08876-0151

Made in Switzerland  
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P19070/B

ETH.MESH.02341522

ENGLISH

# Gynecare

## PROLIFT\*

Total Pelvic Floor Repair System  
Anterior Pelvic Floor Repair System  
Posterior Pelvic Floor Repair System

**Please read all information carefully.**

Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT\* Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training.

**Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair Systems for further information on the GYNECARE PROLIFT procedures.**

**INDICATIONS**

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

**DESCRIPTION**

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH\* PS Nonabsorbable PROLENE\* Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

*Table 1 – GYNECARE PROLIFT Pelvic Floor Repair System Components*

**GYNECARE GYNEMESH PS**

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

**Total Mesh Implant**

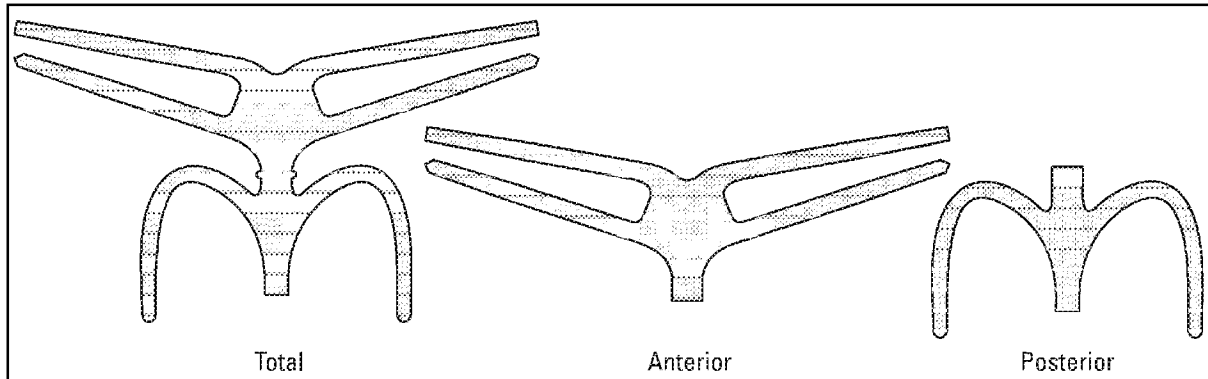
The Total mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends (see Figure 1).

**Anterior Mesh Implant**

The Anterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively (see Figure 1).

### Posterior Mesh Implant

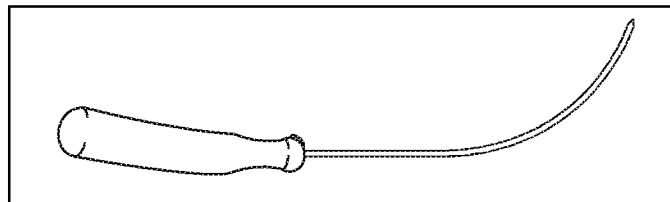
The Posterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends (*see Figure 1*).



**Figure 1 – Mesh Implants (Total, Anterior, and Posterior)**

### GYNECARE PROLIFT Guide

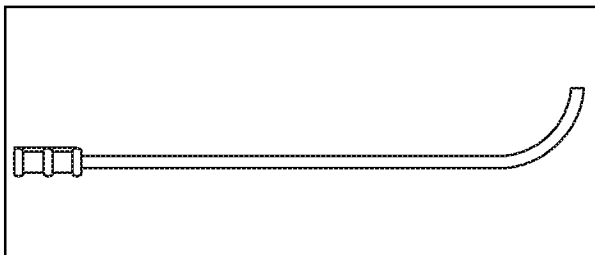
The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient (*see Figure 2*).



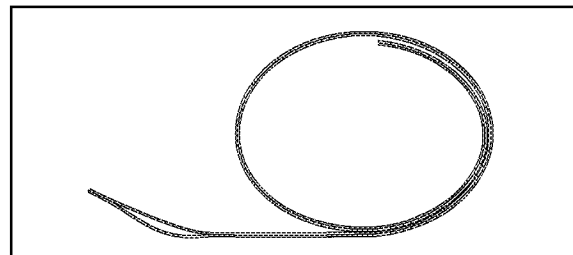
**Figure 2 – GYNECARE PROLIFT Guide**

### GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn (*see Figure 3*).



**Figure 3 – GYNECARE PROLIFT Cannula**



**Figure 4 – GYNECARE PROLIFT Retrieval Device**

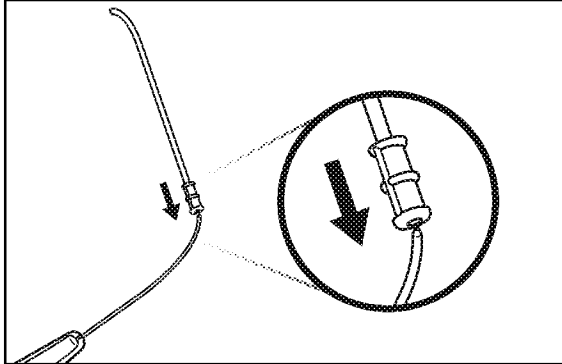
### GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula (*see Figure 4*).

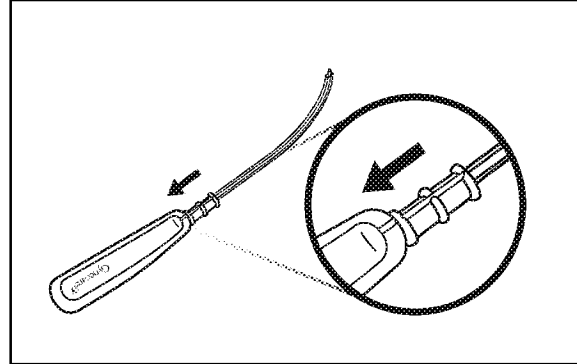
# **INSTRUCTIONS FOR USE**

**NOTE:** All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

**Placement of the the GYNECARE PROLIFT Cannula onto the GYNECARE PROLIFT Guide (See Figures 5A and 5B)**



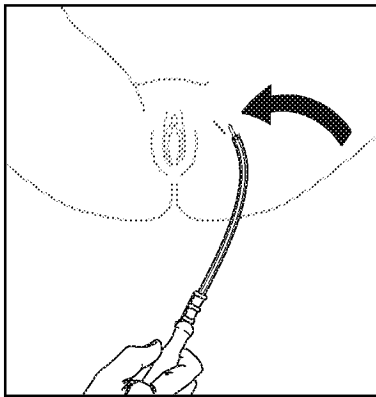
**Figure 5A**



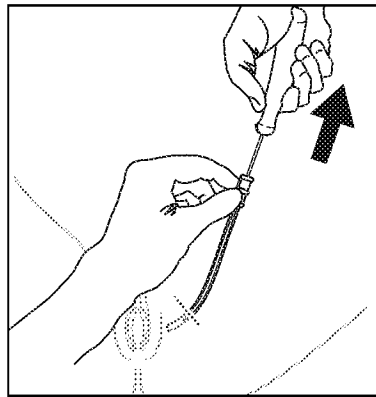
**Figure 5B**

**IMPORTANT:** Ensure proper alignment of GYNECARE PROLIFT Cannula and GYNECARE PROLIFT Guide upon assembly as demonstrated in Figure 5B.

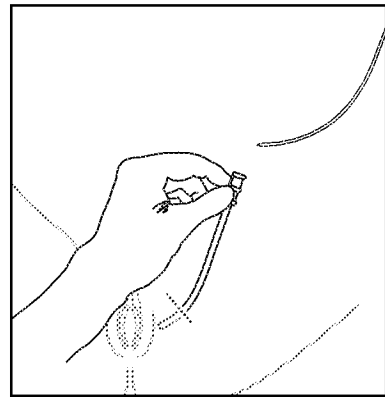
**Placement of the GYNECARE PROLIFT Cannula into the Patient (See Figures 6A , 6B and 6C)**



**Figure 6A**

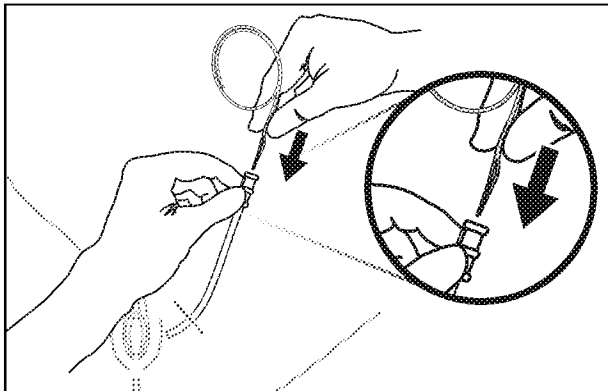


**Figure 6B**

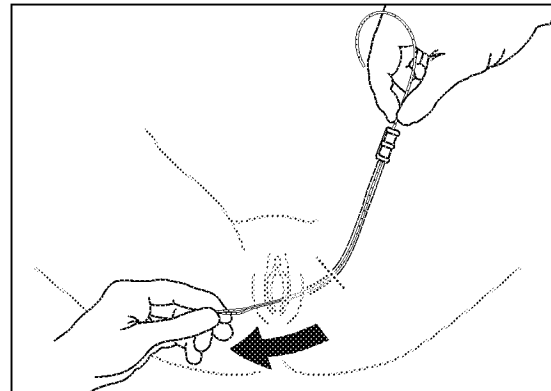


**Figure 6C**

**Insertion and Passage of the GYNECARE PROLIFT Retrieval Device into the GYNECARE PROLIFT Cannula (See Figures 7A and 7B)**



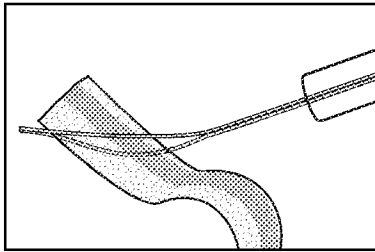
**Figure 7A**



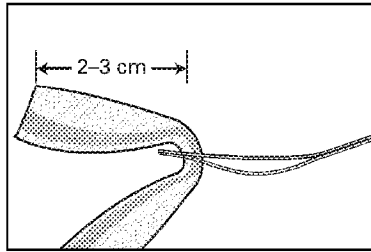
**Figure 7B**

**IMPORTANT:** All provided GYNECARE PROLIFT Cannulas and GYNECARE PROLIFT Retrieval Devices should be placed prior to mesh implant installation.

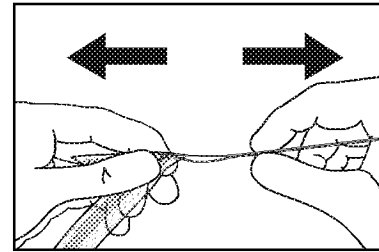
**Capture of a Mesh Implant Strap with GYNECARE PROLIFT Retrieval Device (See Figures 8A , 8B and 8C)**



**Figure 8A**

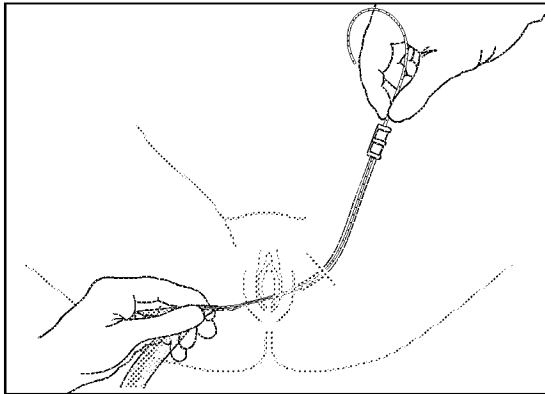


**Figure 8B**

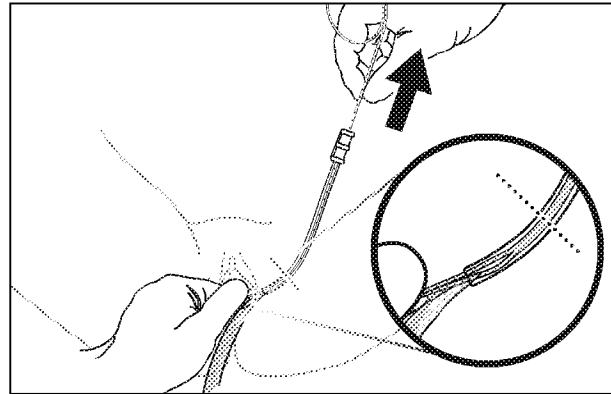


**Figure 8C**

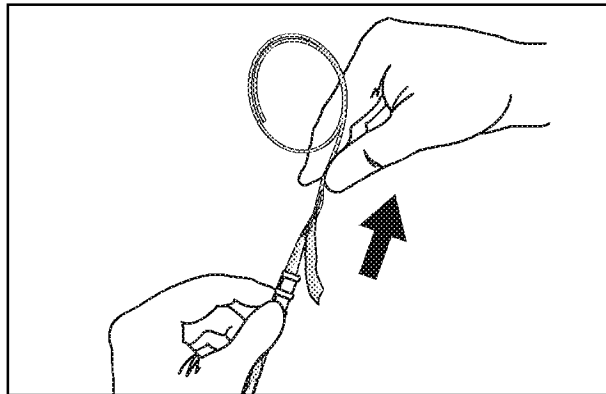
**Passage of a Mesh Implant Strap through the GYNECARE PROLIFT Cannula (See Figures 9A , 9B and 9C)**



**Figure 9A**



**Figure 9B**



**Figure 9C**

**IMPORTANT:** Do not remove the GYNECARE PROLIFT Cannulas from the patient until the mesh implant has been properly positioned.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

**PERFORMANCE**

Animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

## CONTRAINDICATIONS

When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

## WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.
- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

## ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

## STERILITY

The GYNECARE PROLIFT Pelvic Floor Repair Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

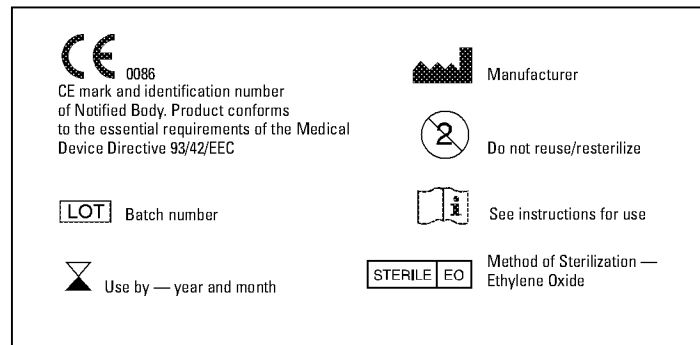
## DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

## STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

### Symbols Used on Labeling



# EXHIBIT B

1           IN THE UNITED STATES DISTRICT COURT  
2           FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3           CHARLESTON DIVISION

4   IN RE: ETHICON, INC.                           Master File No.  
5   PELVIC REPAIR SYSTEMS                       2:12-MD-02327  
6   PRODUCTS LIABILITY LITIGATION           MDL NO. 2327

---

7           Mary Shelton, et al.,               JOSEPH R. GOODWIN  
8   U.S. DISTRICT JUDGE

9                           Plaintiffs,

10          v.                                   Case No. 2:12-cv-01707

11          Ethicon, Inc., et al.,  
12                           Defendants.

13                           ORAL DEPOSITION OF  
14                           CHRISTINA PRAMUDJI, M.D.  
15                           Tuesday, July 12, 2016

16  
17  
18  
19  
20  
21  
22                           GOLKOW TECHNOLOGIES, INC.  
23                           ph 877.370.3377   |   fax 917.591.5672  
24                           deps@golkow.com

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1 erosion.  
2 Q. What's the basis of that  
3 opinion?  
4 A. Because an exposure is more  
5 after -- immediately after the surgery, when  
6 the wound doesn't come together well. An  
7 erosion is further down the line where the  
8 tissue is compromised and breaks down. In  
9 her case, it was compromised by the atrophy.  
10 Q. Other than the atrophy, the  
11 diabetes and the hysterectomy, do you believe  
12 that there's anything that Mary Shelton did  
13 herself to cause or contribute to the  
14 exposure or erosion that she experienced?  
15 A. No.  
16 Q. I've seen in some of the  
17 records a diagnosis of diverticulosis. Do  
18 you recall that?  
19 A. I don't remember off the top of  
20 my head.  
21 Q. Is there anything about that  
22 diagnosis, assuming it exists, that would  
23 have caused or contributed to Mary Shelton's  
24 mesh erosion or exposure?

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1 A. No.  
2 Q. And I think I've also seen a  
3 diagnosis of or treatment for basal cell  
4 carcinoma on her chin. Do you recall seeing  
5 that?  
6 A. I don't remember that.  
7 Q. Assuming that it's there, do  
8 you believe that that would cause or  
9 contribute to her mesh erosion or exposure?  
10 A. No.  
11 MS. COPELAND: How long have we  
12 been going?  
13 THE REPORTER: I can tell you.  
14 57 minutes.  
15 BY MS. COPELAND:  
16 Q. You know what I want to do? I  
17 would like to take a break right now if it's  
18 okay with you.  
19 A. Sure.  
20 Q. Because I've been kind of  
21 jumping all over the place, and then see if I  
22 can pull it all together and wrap it up --  
23 A. Sure.  
24 Q. -- well in advance of two

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1 hours.  
2 A. Sure.  
3 (Recess taken, 6:59 p.m. to  
4 7:09 p.m.)  
5 BY MS. COPELAND:  
6 Q. Let's go back to page 5 of your  
7 report, which is Exhibit 2.  
8 A. Okay.  
9 Q. You indicate at number 5 or you  
10 note at number 5 that Mrs. Shelton continues  
11 to have mild urinary incontinence.  
12 Do you see that?  
13 A. Yes.  
14 Q. And you say it's common at her  
15 age and it is multifactorial. It does not  
16 represent a failure or defect of the mesh.  
17 My question to you is: A  
18 failure or a defect of a mesh, is it a  
19 possibility of her -- a possible cause of her  
20 recurrent incontinence?  
21 A. No, I don't believe so, no.  
22 Q. So when you indicate that the  
23 urinary incontinence is multifactorial, what  
24 do you mean?

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1 A. Well, as women age, urinary  
2 incontinence becomes more common and it's due  
3 to urogenital atrophy, it's due to anatomical  
4 changes. There's numerous causes that can  
5 occur. The diabetes is a factor that can  
6 cause urinary incontinence.  
7 So there's many reasons why she  
8 has urinary incontinence.  
9 Q. But mesh is not one of them?  
10 A. Correct.  
11 Q. You're aware of literature out  
12 there that supports at least the possibility  
13 that mesh or mesh failure can be a cause of  
14 recurrent stress incontinence, correct?  
15 MR. SNELL: Form and  
16 foundation.  
17 A. I don't believe that the mesh  
18 causes it, but I believe that the anatomy can  
19 change over time and the mesh cannot overcome  
20 those changes in anatomy.  
21 BY MS. COPELAND:  
22 Q. I'm not sure if I asked you  
23 this earlier, and I apologize if I did. Is  
24 there anything about Mary Shelton's medical

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1 history, medical condition in 2002, at the  
2 time of her implant, to suggest she was not a  
3 proper candidate for either of the mesh  
4 products implanted in her body?  
5 A. No.  
6 Q. There was no warning or  
7 contraindication that you're aware of in  
8 either of the IFUs to suggest that those  
9 products should not have been implanted in  
10 her body, correct?  
11 A. Correct.  
12 Q. I saw somewhere that you had  
13 done some work with Ethicon beyond serving as  
14 an expert offering opinions on their behalf,  
15 and what I noted was that you had done some  
16 preceptorship work for Ethicon? Is that  
17 right?  
18 A. Correct.  
19 Q. And that involves teaching  
20 other physicians about the Ethicon  
21 products --  
22 A. Correct.  
23 Q. -- and how to implant them,  
24 right?

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1 A. Yes.  
2 Q. And how to decide what types of  
3 patients are appropriate and which ones are  
4 not appropriate, correct?  
5 A. Correct.  
6 Q. Have you done any preceptorship  
7 work since -- on behalf of Ethicon since you  
8 have been hired to serve as an expert on  
9 their behalf?  
10 A. No.  
11 Q. I noticed -- noted that you had  
12 also served on some advisory panels for  
13 Ethicon.  
14 A. Yes, that's correct.  
15 Q. Have you been on any advisory  
16 panels since you began working as an expert  
17 on their behalf?  
18 A. No.  
19 Q. And appearing at or moderating  
20 meetings or booths or a booth at AUA, have  
21 you done that since you've been hired as an  
22 expert?  
23 A. No.  
24 Q. Other than serving as an

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1 expert, preceptorship work, advisory panels  
2 and moderating meetings or booths at AUA,  
3 have you done any other paid work on behalf  
4 of Ethicon, ever?  
5 MR. SNELL: Object, form.  
6 Covered in prior depositions.  
7 Go ahead.  
8 A. Not that I can recall.  
9 BY MS. COPELAND:  
10 Q. Okay. And that's all -- I'm  
11 just trying to get current, you know, so  
12 maybe something has changed since then, but  
13 thank you.  
14 MR. SNELL: I have no problem  
15 with current questions in that regard,  
16 if that's what you're asking.  
17 MS. COPELAND: Yeah, yeah. I'm  
18 just looking for anything new.  
19 MR. SNELL: Yeah, I have no  
20 issue with current. I just thought I  
21 heard prior, sorry.  
22 MS. COPELAND: And I could have  
23 said it. Thank you.  
24 BY MS. COPELAND:

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1 Q. What I think that I'm going to  
2 do is I want to take -- the only thing that  
3 you brought that causes me any concern would  
4 be the drives, since I can't see them.  
5 MR. SNELL: They just have -- I  
6 mean, I'll put it on the record. I'll  
7 make a representation. They just have  
8 the medical records, all the medical  
9 records and the depositions that would  
10 have been accumulated at that point.  
11 MS. COPELAND: Case-specific  
12 only?  
13 MR. SNELL: Case-specific,  
14 yeah, yeah, yeah.  
15 MS. COPELAND: Okay.  
16 MR. SNELL: Let me plug it in.  
17 MS. COPELAND: And then I'm not  
18 sure what the position is or it's  
19 going to be, but what I would like to  
20 do is I'm going to stop, but I want to  
21 at least put it on the record, a  
22 reservation of my right to finish off  
23 any untaken time to depose you on a  
24 medical examination if you perform

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1 one.  
2 I don't know that you can agree  
3 or disagree, but I want to reserve my  
4 right to do that.  
5 THE REPORTER: Are we still on  
6 the record? Is there anything  
7 further?  
8 MR. SNELL: I'm just looking --  
9 I'm sorry.  
10 MS. COPELAND: Yeah, let's stay  
11 on the record for a few minutes.  
12 MR. SNELL: So, Counsel, my  
13 representation is accurate. I'm  
14 opening up the thumb drive, and all  
15 that are on it are case-specific  
16 medical records and transcripts from  
17 depositions.  
18 MS. COPELAND: In this case.  
19 MR. SNELL: In this case.  
20 MS. COPELAND: Yeah, you said  
21 case-specific.  
22 MR. SNELL: And they would be  
23 contained and set forth, itemized in  
24 the back of the materials list that

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1 you discussed with the doctor earlier.  
2 MS. COPELAND: Great. Okay.  
3 Then with the noting on the record of  
4 my reservation to continue this  
5 deposition if a medical examination is  
6 taken or performed on Mary Shelton, I  
7 will pass the witness.  
8 EXAMINATION  
9 BY MR. SNELL:  
10 Q. Dr. Pramudji, I just have a few  
11 follow-up questions.  
12 You mentioned the rough draft  
13 of Dr. Pizarro and that you had not had a  
14 chance to read that yet? Am I correct in  
15 that regard?  
16 A. That's correct.  
17 Q. Do you plan to review that  
18 deposition?  
19 A. Yes.  
20 Q. Do you plan to review any other  
21 depositions or medical records that become  
22 available between now and the time of trial?  
23 A. Yes.  
24 Q. And if you review any of those

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1 and it changes or augments or change -- or  
2 affects your opinion, will you let me know so  
3 I can let plaintiffs' counsel know?  
4 A. Yes.  
5 MR. SNELL: Counsel, I believe  
6 there was an updated or a supplemental  
7 reliance list that was served a week  
8 or so ago.  
9 MS. COPELAND: Oh, yeah? Okay.  
10 MR. SNELL: I don't know if you  
11 have it or if you want to attach it,  
12 but I will put that on the record.  
13 MS. COPELAND: Can we go ahead  
14 and just mark that as Exhibit 3?  
15 MR. SNELL: Yeah.  
16 MS. COPELAND: Why don't we  
17 just do that.  
18 MR. SNELL: Okay. I don't have  
19 a copy of it, but I assume --  
20 MS. COPELAND: We'll get one.  
21 MR. SNELL: Okay.  
22 (Whereupon, Exhibit  
23 Pramudji-Shelton-3, Supplemental  
24 Reliance List in Addition to Materials

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1 Referenced in Report Re Mary Shelton,  
2 was marked for identification.)  
3 BY MR. SNELL:  
4 Q. You were asked a question about  
5 whether all of the general materials in your  
6 prior general report are the entire scope of  
7 your general opinions.  
8 Do you recall a question  
9 somewhat along those lines?  
10 A. Yes.  
11 Q. I'm paraphrasing because  
12 plaintiffs' counsel's question was much more  
13 articulate than that one.  
14 MS. COPELAND: One of them.  
15 BY MR. SNELL:  
16 Q. My question to you is this,  
17 Doctor: Have you, since the time of your  
18 most recent general Gynemesh Prolift report,  
19 continued to review the literature with  
20 regard to those products?  
21 A. Yes.  
22 Q. And have you, in prior  
23 depositions, noted the additional materials  
24 that you have reviewed that don't change your

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1 opinion but are just further supportive of  
2 your opinions?  
3 A. Yes.  
4 Q. Such as the recent AUGS, SUFU,  
5 AUA, SGS, National Incontinence Group,  
6 position statement that was just released on  
7 midurethral slings?  
8 A. Yes.  
9 Q. The paper to be presented at  
10 IUGA on the lack of support for a degradation  
11 theory showing that the correct material is  
12 instead a biologic proteinaceous material?  
13 A. Yes.  
14 MS. COPELAND: Objection, form.  
15 BY MR. SNELL:  
16 Q. Do you recall the questions  
17 about the mesh erosion, in particular where  
18 it was located?  
19 A. Yes.  
20 Q. I believe you testified it was  
21 reported in the records to be 1-point --  
22 strike that.  
23 The mesh exposure or erosion  
24 was reported to be approximately

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1 1-by-1 centimeters at the apex? Do you  
2 recollect giving that testimony?  
3 A. Yes.  
4 Q. Was the mesh erosion at the  
5 site of the TVT, or was that the prolapsed  
6 mesh?  
7 A. That would be the prolapsed  
8 mesh.  
9 Q. Do you recall being asked about  
10 whether or not generally mesh is supposed to  
11 erode?  
12 A. Yes.  
13 Q. Is erosion a potential risk of  
14 utilizing sutures?  
15 A. Yes.  
16 Q. Is it a potential risk of using  
17 biologic materials?  
18 A. Yes, it is.  
19 Q. Is it a potential risk of using  
20 autologous material?  
21 A. Yes.  
22 Q. Is that all set forth in your  
23 general report?  
24 A. Yes.

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1 Q. Do you recall being asked about  
2 the plaintiff's shortened and narrowed  
3 vagina?  
4 A. Yes.  
5 Q. Was that a preexisting  
6 condition she had even before her 2002  
7 surgeries with the Prolene and TVT?  
8 A. Yes, that's correct.  
9 Q. Did you consider that in  
10 formulating your differential diagnoses?  
11 A. Yes.  
12 Q. Was dyspareunia a preexisting  
13 medical condition?  
14 A. Yes, it was.  
15 Q. And when I say "preexisting,"  
16 I'm asking, did it preexist as well the  
17 mesh-based repairs from 2002?  
18 A. Yes.  
19 Q. And did she have the  
20 dyspareunia at the same time she had the  
21 shortened and narrowed vagina before the 2002  
22 mesh-based repair surgeries with the TVT and  
23 Prolene?  
24 MS. COPELAND: Form.

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1 A. Yes.  
2 BY MR. SNELL:  
3 Q. Did you consider that in  
4 formulating your differential diagnosis?  
5 A. Yes.  
6 Q. You were asked a question about  
7 the recurrence noted in 2010 and plaintiff's  
8 complaint of recurrent prolapse. My question  
9 to you is this: I believe in your report you  
10 note that the prolapse in 2010 was at a  
11 rectocele and enterocele?  
12 A. That's correct.  
13 Q. Where was the Prolene mesh used  
14 back in 2002?  
15 A. The Prolene mesh was used in  
16 the anterior compartment of the vagina to  
17 repair a cystocele, so it's a different wall  
18 of the vagina.  
19 Q. Would the rectocele/enterocele  
20 noted in 2010 be a recurrence of that  
21 anterior colporrhaphy/replacement of Prolene  
22 mesh performed in 2002?  
23 MS. COPELAND: Objection, form.  
24 A. No.

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1 BY MR. SNELL:  
2 Q. As far as that rectocele  
3 recurring, when did she first actually have  
4 her initial rectocele repair? And I'm  
5 looking at your report at the top of page 2.  
6 A. 1986.  
7 Q. And then between 1986 and 2002,  
8 she also had numerous other rectocele  
9 repairs?  
10 A. That's correct.  
11 Q. And then in 2010, she had  
12 another rectocele noted?  
13 A. That's correct.  
14 Q. And would that be a recurrence  
15 of her earlier rectocele repairs and  
16 preexisting history of a rectocele?  
17 MS. COPELAND: Objection, form.  
18 A. Yes, that's correct.  
19 BY MR. SNELL:  
20 Q. Was the rectocele a documented  
21 preexisting medical condition that she had  
22 before the 2002 surgeries with the TVT and  
23 the Prolene mesh for anterior repair?  
24 MS. COPELAND: Objection, form.

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1 A. Yes, that's correct.  
2 BY MR. SNELL:  
3 Q. You were asked about the  
4 defecatory dysfunction also that she reported  
5 at the same time as her rectocele in 2010.  
6 Do you recall that?  
7 A. Yes.  
8 Q. And you testified it was not  
9 from the mesh. Do you recall that?  
10 A. Yes.  
11 Q. What, if anything, do you  
12 believe that that defecatory dysfunction was  
13 from?  
14 MR. SNELL: Objection, form.  
15 A. I believe that was from the  
16 recurrent rectocele.  
17 BY MR. SNELL:  
18 Q. Okay. You were asked a  
19 question about the IFUs and what it said or  
20 didn't say.  
21 Do you recall that?  
22 A. Yes.  
23 Q. Did the Prolene and TVT IFUs  
24 warn of the risk of erosion, extrusion?

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1 MS. COPELAND: Objection, form.  
2 A. Yes.  
3 BY MR. SNELL:  
4 Q. Did they warn of the risk of  
5 inflammation?  
6 A. Yes.  
7 Q. Based on your review of the  
8 literature -- strike that.  
9 Plaintiffs' counsel asked you  
10 questions about your various professional  
11 education activities with Ethicon on their  
12 products. Do you recall that?  
13 A. Yes.  
14 Q. Does the IFUs also recommend a  
15 surgeon undergo training?  
16 A. Yes.  
17 Q. Does that professional  
18 education and training also warn or advise of  
19 the risk of erosion, extrusion, inflammation?  
20 MS. COPELAND: Objection, form.  
21 A. Yes.  
22 BY MR. SNELL:  
23 Q. Does it warn of other risks?  
24 MS. COPELAND: Objection, form.

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1 A. Yes.  
2 BY MR. SNELL:  
3 Q. Page 4 of your report, you cite  
4 to a paper by Iglesia regarding the use of  
5 mesh in gynecologic surgery published in  
6 1997. Do you see that?  
7 A. Yes.  
8 Q. And you state, "As noted in my  
9 general report, wound complications, scarring  
10 and dyspareunia are risks of all prolapse  
11 surgeries that have been long reported in the  
12 literature." Is that correct?  
13 MS. COPELAND: Objection, form.  
14 A. Yes.  
15 BY MR. SNELL:  
16 Q. "And are a basic part of pelvic  
17 floor surgeon training." Do you recall that?  
18 A. Yes.  
19 Q. Through your review of the  
20 literature over the years and your medical  
21 education and training, are you aware of what  
22 risks or complications would be commonly  
23 known to the intended users of these devices?  
24 MS. COPELAND: Objection, form.

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1 A. Yes.  
2 BY MR. SNELL:  
3 Q. And would mesh  
4 erosion/exposure, dyspareunia, scarring, are  
5 those risks that would be commonly known to  
6 the intended user of these devices at the  
7 time of Mrs. Shelton's surgery?  
8 MS. COPELAND: Objection, form.  
9 A. Yes.  
10 BY MR. SNELL:  
11 Q. Is that based on your review of  
12 the literature over decades as well as your  
13 experience and education as well as  
14 professional education, teaching and training  
15 activities with the Ethicon products?  
16 MS. COPELAND: Objection, form.  
17 A. Yes.  
18 MR. SNELL: That's all I have.  
19 FURTHER EXAMINATION  
20 BY MS. COPELAND:  
21 Q. It's not your opinion that the  
22 size 0 Ethibond sutures utilized in  
23 Mrs. Shelton at the time of her prolapse  
24 surgery with mesh was a cause or contributing

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1 factor to her erosion or exposure, is it?  
2 A. No.  
3 Q. Do you believe that there is  
4 any biologic material that's ever been  
5 implanted in Mrs. Shelton that caused or  
6 contributed to her erosion or exposure?  
7 A. No.  
8 Q. What about autologous material?  
9 Do you believe that there's any autologous  
10 material that's ever been used in any of her  
11 surgeries that caused or contributed to her  
12 exposure or erosion?  
13 A. No.  
14 Q. And then on page 4 of your  
15 report, going back to that citation to the  
16 Iglesia article, you would agree with me --  
17 let me back up and just get this right.  
18 You note that wound  
19 complications, scarring and dyspareunia are  
20 risks of all prolapse surgeries that have  
21 long been reported in the literature,  
22 correct?  
23 A. Correct.  
24 Q. You would agree with me that

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1 mesh is also one of the prolapse surgeries to  
2 which you refer, correct?  
3 A. Correct.  
4 Q. So you would agree with me that  
5 wound complications are a risk of mesh  
6 prolapse surgery, correct?  
7 MR. SNELL: Object, form.  
8 Go ahead.  
9 A. Correct.  
10 BY MS. COPELAND:  
11 Q. And scarring is a risk  
12 associated with mesh prolapse surgery,  
13 correct?  
14 A. Correct.  
15 Q. And finally, dyspareunia is a  
16 risk associated with mesh prolapse surgery,  
17 correct?  
18 A. Correct.  
19 MS. COPELAND: That's all I've  
20 got. Thank you.  
21 THE WITNESS: Okay. Thank you.  
22 MR. SNELL: That's all I have.  
23 THE REPORTER: The reporter  
24 will put the elapsed time on the

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1 record, and we are off the record at  
2 7:31.  
3 (Deposition recessed at  
4 7:31 p.m.)  
5 REPORTER'S NOTE: Examination  
6 time used by counsel is as follows:  
7 BY MS. COPELAND: 01:07:14  
8 BY MR. SNELL: 00:12:36  
9 --oOo--  
10  
11  
12  
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15  
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24

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# CERTIFICATE

I, SUSAN PERRY MILLER, Registered  
Diplomate Reporter, Certified Realtime  
Reporter, Certified Court Reporter and Notary  
Public, do hereby certify that prior to the  
commencement of the examination, CHRISTINA  
PRAMUDJI, M.D. was duly sworn by me to  
testify to the truth, the whole truth and  
nothing but the truth;

That pursuant to Rule 30 of the Federal Rules of Civil Procedure, signature of the witness was not reserved by the witness or other party before the conclusion of the deposition;

That the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Susan Perry Miller  
CSR-TX, CCR-LA, CSR-CA  
Registered Diplomat Reporter  
Certified Realtime Reporter  
Certified Realtime Captioner  
NCRA Realtime Systems Administrator  
Notary Public, State of Texas  
My Commission Expires 03/30/2016

Dated: 18th of July, 2016

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## LAWYER'S NOTES

PAGE    LINE

[illegible]

# EXHIBIT C

1 UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT WEST VIRGINIA  
2 CHARLESTON DIVISION  
3 ) Master File  
IN RE: ETHICON, INC., ) No. 2:12-MD-02327  
4 PELVIC REPAIR SYSTEM ) MDL No. 2327  
PRODUCTS LIABILITY )  
5 LITIGATION ) JOSEPH R. GOODWIN  
\_\_\_\_\_) U.S. DISTRICT JUDGE  
6 ) \_\_\_\_\_  
THIS DOCUMENT RELATES TO )  
7 PLAINTIFFS: )  
)  
8 Donna Bihlmeyer, et al v. )  
Ethicon, Inc., et al )  
9 )  
Case No. 2:12-cv-02159 )

10  
11 \*\*\*\*\*  
12 VIDEO DEPOSITION OF  
13 CHRISTINA KLEIN PRAMUDJI, M.D.  
14 June 9, 2016  
15 \*\*\*\*\*  
16  
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21  
22  
23  
24

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1 scarring that led to the vaginal stenosis. Was that  
2 scarring worse in the native tissue arm than the  
3 Prolift arm?  
4 A. Yes, it was.  
5 MR. DARLEY: Object to form. Burt, can  
6 we ask some non-leading questions here? I think that  
7 would be appropriate.  
8 Q. (By Mr. Snell) Plaintiff's counsel asked you  
9 some questions about the early Prolift IFU. Do you  
10 recollect that?  
11 A. Yes.  
12 Q. And I believe you testified it was your  
13 opinion that this IFU was adequate?  
14 A. Yes.  
15 Q. And you identified to Plaintiff's counsel  
16 that the IFU points to things like infection,  
17 adhesions, scarring --  
18 MR. DARLEY: Object to form.  
19 Q. (By Mr. Snell) -- and contraction. Is that  
20 correct or not?  
21 A. Yes, that's what I -- that's what I pointed  
22 to.  
23 Q. And why is it your opinion that a pelvic  
24 floor surgeon would understand that dyspareunia could

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1 flow from any of those complications?  
2 A. Because we are trained to know that scarring  
3 in the vagina and inflammation in the vagina will or  
4 can, it may not, but it can cause dyspareunia. So  
5 that is something that is a fundamental part of  
6 training to pelvic floor surgeons.  
7 Q. Is that -- do you know whether or not the  
8 potential risk of dyspareunia from Prolift surgery,  
9 whether or not that was something that was commonly  
10 known in your field before Prolift came out in 2005?  
11 MR. DARLEY: Object to form.  
12 A. Yes, that was commonly known to occur just  
13 with the most fundamental surgery, such as an anterior  
14 and posterior repair or a hysterectomy, which can be a  
15 form of reconstruction if they have prolapse.  
16 Q. (By Mr. Snell) And in your general report  
17 and in your materials list, do you point to any of the  
18 medical literature that supports that opinion?  
19 A. Yes.  
20 Q. I'd like to hand you a paper from one of the  
21 boxes. Can you identify this for the record?  
22 A. Yes. This is a study dating back to 1961.  
23 The first author is Winifred Francis and the title of  
24 the study is Dyspareunia Following Vaginal Operations.

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1 Q. And what is the significance, if any, of that  
2 study?  
3 MR. DARLEY: Object to outside the scope  
4 of direct.  
5 A. This study shows that, going back over 50  
6 years, that pelvic floor surgeons are aware that  
7 dyspareunia -- and I'm reading from the study -- are  
8 well accepted complications of operations which  
9 involve incision and suture of the vagina, that there  
10 is tenderness of scars in the vaginal walls,  
11 shortening of the vagina, especially following vaginal  
12 hysterectomy is an important factor, but the most  
13 important cause -- obvious cause is narrowing of the  
14 introitus and the vagina, which results from removal  
15 of tissue as part of the cure of prolapse.  
16 Q. (By Mr. Snell) And does this study support  
17 your opinion with regard to the adequacy of the IFU  
18 for Prolift?  
19 A. Yes, this shows that this is part of the  
20 common knowledge and literature of pelvic floor  
21 surgery, vaginal surgery.  
22 Q. And you -- I believe you mentioned in  
23 response to Plaintiff's counsel's questions, you  
24 mentioned the surgeon's monograph. Did I hear you

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1 correctly?  
2 A. Yes, I did.  
3 Q. Well, let me ask you this: Is the surgeon's  
4 monograph part of professional education for Prolift?  
5 A. Yes, it is.  
6 Q. How do you know that?  
7 A. Well, I was -- I did professional education  
8 for Ethicon for many years, so I'm familiar with the  
9 -- what was supplied during the education sessions,  
10 the monograph, IFU, the slide presentations that were  
11 -- that were given, because I was directly involved in  
12 educating other surgeons.  
13 Q. Did you do any professional education on  
14 Prolift?  
15 A. Oh, yes, I did, quite a bit.  
16 Q. During your professional education of the  
17 Ethicon devices, did you cover the instructions for  
18 use?  
19 A. Yes.  
20 Q. And is that a form -- strike that.  
21 Is that part of the foundation of your  
22 opinions about the adequacy of the IFU?  
23 A. Yes.  
24 Q. And if you look at the very first page of the

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1 Prolift IFU that Plaintiff's counsel asked you about,  
2 it says: Training on the use of Gynecare Prolift  
3 Pelvic Floor Repair Systems is recommended and  
4 available.  
5 Do you see that?  
6 A. Yes.  
7 Q. And would a pelvic floor surgeon going to the  
8 Prolift professional education be informed about risk  
9 of scarring, pain and dyspareunia, among others?  
10 MR. DARLEY: Object to form.  
11 A. Yes, we would definitely educate the other  
12 physicians about that.  
13 Q. (By Mr. Snell) And what is the basis of that  
14 statement?  
15 A. That's based on my experience and also just  
16 going back and reviewing the slide presentations and  
17 the monograph and everything that was provided to the  
18 surgeons.  
19 Q. I'm going to hand you the Prolift monograph  
20 that I believe you referenced. Can you tell us  
21 whether that -- whether or not the Prolift monograph  
22 supports your opinion that the IFU is adequate?  
23 MR. DARLEY: Object to form. Leading.  
24 A. Yes, it --

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1 MR. SNELL: Well, it's a whether or not,  
2 so it's one way or the other.  
3 Q. (By Mr. Snell) Go ahead.  
4 A. Yes, it does support my opinion.  
5 Q. Can you tell us why, if at all?  
6 A. Yes. The monograph goes into great detail in  
7 the risks of dyspareunia and vaginal pain with the  
8 Prolift System. It has almost a full page of  
9 information regarding that provided to the surgeons.  
10 It has a graph and it has literature articles to cite  
11 back to if the surgeons wanted more information.  
12 Q. You were asked some questions about  
13 Dr. Galloway's recent IME of the Plaintiff. Do you  
14 recollect that?  
15 A. Yes.  
16 Q. Do you have an understanding as to when  
17 Dr. Galloway did his IME?  
18 A. Yes. It was last week, June 3rd, 2016.  
19 Q. Do you put much weight on Dr. Galloway's IME  
20 considering what -- considering his inability to do an  
21 adequate exam that you mentioned on numerous  
22 occasions?  
23 A. No, I don't.  
24 Q. And I think you made it clear to Plaintiff's

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1 counsel that you would like to do an IME since  
2 Dr. Galloway was afforded that opportunity last week?  
3 A. Yes, I believe I provided dates two or three  
4 weeks ago to open up for an IME, but she was not made  
5 available for that. I would still like that  
6 opportunity.  
7 MR. DARLEY: Object to form. Move to  
8 strike that. Go ahead, Burt.  
9 MR. SNELL: Now, I don't -- Counsel, you  
10 can correct me if I'm wrong, but I don't believe  
11 Dr. Galloway has been deposed yet or maybe he's being  
12 deposed pretty soon.  
13 MR. DARLEY: I think today, actually.  
14 MR. SNELL: Okay.  
15 Q. (By Mr. Snell) Dr. Pramudji, do you intend  
16 to review and comment about Dr. Galloway's deposition  
17 testimony, if at all?  
18 A. Yes.  
19 Q. Okay. Given the data cited in your report at  
20 Page 6 and 7 and the randomized control trials you've  
21 referenced, are you able to rule out the mesh as being  
22 a cause of her dyspareunia and pelvic pain?  
23 A. Yes.  
24 MR. DARLEY: Object to form.

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1 Q. (By Mr. Snell) What do you believe to be the  
2 cause of her pelvic pain and dyspareunia?  
3 MR. DARLEY: Object to form.  
4 A. I believe that her pelvic pain and  
5 dyspareunia is due to scarring from the hysterectomy  
6 and the pelvic floor reconstruction and in recent  
7 months or years is due to the vaginal atrophy that she  
8 has developed over the last few years.  
9 Q. (By Mr. Snell) And for the vaginal atrophy  
10 that you mentioned, is that a treatable condition?  
11 A. Yes, it is.  
12 Q. How, if at all, would you recommend  
13 Mrs. Bihlmeyer consider treating the atrophy?  
14 A. I would recommend that she use either a  
15 vaginal cream, like Premarin cream or Estrace cream,  
16 she could use a vaginal tablet, such as Vagifem or she  
17 could use Osphena, which is an oral tablet. And any  
18 of those treatments would improve her vaginal wall  
19 health and the sensations would improve.  
20 MR. SNELL: That's all I have. Thank  
21 you.  
22 EXAMINATION  
23 QUESTIONS BY MR. DARLEY:  
24 Q. Dr. Pramudji, I've just got a couple more

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1 I, CHRISTINA KLEIN PRAMUDJI, M.D, have read the  
2 foregoing deposition and hereby affix my signature  
3 that same is true and correct, except as noted above.  
4  
5

CHRISTINA KLEIN PRAMUDJI, M.D

THE STATE OF \_\_\_\_\_)

8 COUNTY OF \_\_\_\_\_)

9 Before me, \_\_\_\_\_, on this  
10 day personally appeared CHRISTINA KLEIN PRAMUDJI, M.D,  
11 known to me (or proved to me under oath or through  
12 \_\_\_\_\_) (description of identity

13 card or other document) to be the person whose name is  
14 subscribed to the foregoing instrument and  
15 acknowledged to me that they executed the same for the  
16 purposes and consideration therein expressed.

17 Given under my hand and seal of office this  
18 \_\_\_\_\_ day of \_\_\_\_\_,  
19 \_\_\_\_\_.

NOTARY PUBLIC IN AND FOR

THE STATE OF \_\_\_\_\_

COMMISSION EXPIRES: \_\_\_\_\_

Page 107

1 THE STATE OF TEXAS:  
2 COUNTY OF FT. BEND:

3 I, Tamara Vinson, a Certified Shorthand  
4 Reporter and Notary Public in and for the State of  
5 Texas, do hereby certify that the facts as stated by  
6 me in the caption hereto are true; that the above and  
7 foregoing answers of the witness, CHRISTINA KLEIN  
8 PRAMUDJI, M.D., to the interrogatories as indicated were  
9 made before me by the said witness after being first duly  
10 sworn to testify the truth, and same were reduced to  
11 typewriting under my direction; that the above and  
12 foregoing deposition as set forth in typewriting is a  
13 full, true, and correct transcript of the proceedings  
14 had at the time of taking of said deposition.

15 I further certify that I am not, in any  
16 capacity, a regular employee of the party in whose  
17 behalf this deposition is taken, nor in the regular  
18 employ of his attorney; and I certify that I am not  
19 interested in the cause, nor of kin or counsel to  
20 either of the parties.

21 GIVEN UNDER MY HAND AND SEAL OF OFFICE, on  
22 this, the \_\_\_\_ day of June, 2016.

Tamara Vinson, Texas CSR No. 3015  
Expiration Date: 12-31-2016

23 GOLKOW TECHNOLOGIES, INC.  
24 Texas CRCB Registration #690  
440 Louisiana, Suite 910  
Houston, Texas 77002  
www.golkow.com

# EXHIBIT D

# Complication and Reoperation Rates After Apical Vaginal Prolapse Surgical Repair

## A Systematic Review

Gouri B. Diwadkar, MD, Matthew D. Barber, MD, MHS, Benjamin Feiner, MD, Christopher Maher, MD, and J. Eric Jelovsek, MD

**OBJECTIVE:** To compare postoperative complication and reoperation rates for surgical procedures correcting apical vaginal prolapse.

**DATA SOURCES:** Eligible studies were selected through an electronic literature search covering January 1985 to January 2008 using PubMed, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews and Effects.

**METHODS OF STUDY SELECTION:** Only clinical trials and observational studies addressing apical prolapse repair and recurrence or complication rates were included. The search was restricted to original articles published in English with 50 or more participants and a follow-up period of 3 months or longer. Oral platform and poster presentations from the American Urogynecological Society, the Society for Gynecologic Surgeons, the International Urogynecological Association, and the International Continence Society from January 2005 to December 2007 were hand searched to determine whether they were eligible for inclusion.

**TABULATION, INTEGRATION, AND RESULTS:** Procedures were separated into three groups: traditional vaginal surgery, sacral colpopexy, and vaginal mesh kits. Complications were classified using the Dindo grading system. Weighted averages were calculated for each Dindo grade, complication, and reoperation. Dindo

grade IIIa (433/3,425 women) and IIIb (245/3,425) rates were highest in the mesh kit group owing to higher rates of mesh erosion (198/3,425) and fistulae (8/3,425). Reoperation rates for prolapse recurrence were highest in the traditional vaginal surgery group (308/7,827). The total reoperation rate was greatest in the mesh kit group (291/3,425, 8.5%).

**CONCLUSION:** The rate of complications requiring reoperation and the total reoperation rate was highest for vaginal mesh kits despite a lower reoperation rate for prolapse recurrence and shorter overall follow-up.

(*Obstet Gynecol* 2009;113:367–73)

Pelvic organ prolapse often involves a combination of support defects involving the anterior, posterior, and apical vaginal segments. There is growing recognition that adequate support for the vaginal apex is an essential component of a durable surgical repair for women with advanced prolapse.<sup>1–3</sup> The Surgery for Pelvic Organ Prolapse Committee of the 3rd International Consultation on Incontinence noted that “the apex is the keystone of pelvic organ support . . . the best surgical correction of the anterior and posterior walls is doomed to failure unless the apex is adequately supported.”<sup>1</sup> Restoring the anatomy of the vaginal apex by apical suspension can be achieved by several techniques, with the “gold standard” being sacral colpopexy.<sup>4</sup> Traditional vaginal approaches include sacrospinous ligament fixation, uterosacral ligament suspension, iliococcygeus muscle suspension, and McCall’s culdoplasty. More recently, commercially available vaginal mesh kits that use trocars to place permanent mesh transvaginally have gained in popularity.<sup>5</sup> However, none of these techniques is without risks for complications or prolapse recurrence.

Data are lacking that compare complication and recurrence rates of traditional procedures with vaginal mesh kits. We hypothesize the following: 1) sacral

From the Cleveland Clinic, Cleveland, Ohio; and Wesley Hospital, Brisbane, Queensland, Australia.

Presented at the American Urogynecologic Society 29th Annual Scientific Meeting, September 4–6, 2008, Chicago, Illinois.

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### Financial Disclosure

The authors did not report any potential conflicts of interest.

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ISSN: 0029-7844/09



colpopexy and traditional vaginal surgeries have fewer operative complications compared with vaginal mesh kits, and 2) recurrent prolapse rates are higher in the traditional vaginal surgery group compared with the vaginal mesh kit group. The objective of this meta-analysis is to compare complication and prolapse recurrence rates after sacral colpopexy, traditional vaginal surgeries, and vaginal mesh kits that aim to repair prolapse of the vaginal apex.

## SOURCES

Eligible studies were selected through an electronic literature search from January 1985 to January 2008 using PubMed, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews and Effects, and the ACP Journal Club. The search strategy was formulated and conducted with the assistance of a professional medical research librarian. Search terms included the following keywords and phrases: “vaginal prolapse and surgery,” “uterine prolapse and (complications or prevention) and (control or surgery or therapy),” “uterosacral,” “sacrospinous,” “sacrospinous ligament,” “sacrocolpopexy,” “sacral colpopexy,” “colpopexy,” “sacropexy,” “sacro-uteropexy,” “iliococcygeus,” “prolift,” “apogee,” “avaulta,” “vaginal vault and prolapse,” “apical vaginal and prolapse,” “vaginal mesh,” and “vaginal mesh and prolapse.” Keywords appeared in the title, abstract, or both.

## STUDY SELECTION

The search was restricted further to original articles published in English that included 50 or more participants and had a follow-up period of 3 months or longer. Only clinical trials and observational studies addressing apical prolapse repair and associated recurrence or complication rates were included. Case reports were excluded. If data were published in multiple studies, the study with the longest follow-up period was selected for inclusion. Oral platform and poster presentations from the American Urogynecological Society, the Society for Gynecologic Surgeons, the International Urogynecological Association, and the International Continence Society from January 2005 to December 2007 were hand searched to determine whether they were eligible for inclusion. Reference lists from review articles and sentinel trials were searched for additional studies.

Two independent reviewers assessed eligibility and abstracted data from each study. In cases of discordance between reviewers regarding study eligibility, differences were discussed until a consensus

was reached. If unable to reach a consensus, a third reviewer intervened to make a final decision. Data were abstracted using a standardized form. Meta-Analysis of Observational Studies in Epidemiology guidelines were followed.<sup>6</sup>

The studies were separated into three groups: 1) traditional vaginal procedures, 2) sacral colpopexy, and 3) vaginal mesh kits. Traditional procedures included uterosacral ligament suspension, sacrospinous ligament suspension, iliococcygeus fascial suspension, and McCall’s culdoplasty. The sacral colpopexy group included standard sacral colpopexies as well as sacrocervicopexies and sacrohysteropexies by laparoscopy or laparotomy. The vaginal mesh kit group included Apogee (American Medical Systems, Inc., Minnetonka, MN), Posterior Gynecare Prolift System and Total Gynecare Prolift System (Ethicon Women’s Health and Urology, Somerville, NJ), Total Vaginal Mesh and Posterior Intravaginal Slingplasty (Tyco Healthcare, United States Surgical, Norwalk, CT), and other miscellaneous transvaginal approaches to support the apex involving permanent mesh. For Total Prolift, we attempted to distinguish between the anterior and apical (includes Posterior Prolift) outcomes. Studies were excluded if it was difficult to make this distinction clearly. In the case of a study with multiple treatment arms, each arm was classified into one of the corresponding groups outlined above.

Complications were classified using the Dindo grading guidelines,<sup>7</sup> which is a valid surgical-complication grading system based on the invasiveness of an intervention used to treat a complication (Table 1). For complications that were unable to be classified clearly using this system, a Dindo grade was assigned before abstraction to prevent discrepancies between reviewers. Because hemorrhage rarely was defined by authors, any reported case of “hemorrhage” or “hematoma” was classified as a “hemorrhage” for the purposes of this study. Pulmonary complications included any case of pneumonia, acute respiratory distress syndrome, or pulmonary edema. Cardiac complications included myocardial infarction, congestive heart failure, and arrhythmias. Injuries to the bowel, bladder, or ureters were classified as “visceral injuries.” Complications excluded from the meta-analysis included bladder symptoms unrelated to visceral injury, fecal incontinence, complications unrelated to the apical prolapse surgery such as anesthesia complications (eg, spinal headache), and complications that unequivocally resulted from concomitant procedures. Treatment was not always specified for patients with mesh erosion. Therefore, we assumed



**Table 1. Dindo Grading**

Dindo Grade	Criteria
I*	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or radiological interventions Includes wound infections opened at the bedside Includes drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy
II	Requiring pharmacological treatment with drugs other than those allowed for grade I complications Includes blood transfusions and total parenteral nutrition
IIIa	Requiring surgical, endoscopic, or radiological intervention not under general anesthesia
IIIb	Requiring surgical, endoscopic, or radiological intervention under general anesthesia
IVa	Life-threatening complication requiring intensive care unit management—single organ dysfunction (includes dialysis)
IVb	Life-threatening complication requiring intensive care unit management—multiorgan dysfunction
V	Death

Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004;240:205–13. Copyright 2004 Lippincott Williams & Wilkins.  
 \* Hematoma, pain, dyspareunia, and fever were assigned Dindo grade I if intervention was not specified.

that 50% of participants were treated medically (Dindo II) and the remaining 50% were treated surgically under anesthesia (Dindo IIIb). If erosion management was treated in the office setting, 50% of participants were assumed to be treated medically (Dindo II) and the remaining participants were treated surgically without general anesthesia (Dindo IIIa). Sensitivity analyses were performed, varying these rates between 25% and 75% to evaluate the effect of our a priori assumptions. Because multiple prolapse grading systems and varying definitions of prolapse recurrence were used throughout the studies, we could not compare anatomic prolapse recurrence between the surgical groups. However, we were able to collect reoperations for prolapse recurrence. Weighted averages and confidence intervals were calculated for Dindo grades, complications, reoperations for prolapse recurrence, and total reoperations (complications treated surgically under general anesthesia [Dindo IIIb] and surgery for prolapse recurrence). Because the focus of this report is on complications and there were few clinical trials comparing the three approaches, no other formal meta-analytic techniques were used beyond the weighted averages described above. Statistics were calculated using JMP 7.0 (SAS Institute, Cary, NC).

**RESULTS**

A total of 249 peer-reviewed articles and 19 conference abstracts met the initial search criteria. Of those, 162 articles were excluded by reviewers because they did not meet the predefined inclusion criteria. A total of 106 studies were included in the meta-analysis, of which 19 were conference abstracts. The characteristics of included and excluded studies are in the Appendix, available online at <http://links.lww.com/A646>. Table 2 summarizes the weighted averages and

confidence intervals for complications, Dindo grades, prolapse reoperation rates, and total reoperation rates.

The traditional vaginal surgery group included 7,827 patients from 48 studies and had the longest follow-up period of 32.6±19.8 months. Of the 48 studies, 35 addressed sacrospinous ligament suspension, eight uterosacral ligament suspension, three iliococcygeus suspension, and two McCall’s culdoplasty. The mean total complication rate for this group was 15.3% (range 0–52.8). The majority of complications in this group required pharmacologic intervention (6.9%) or did not require any intervention (6.2%). The most common complications included urinary tract infection (3.5%), hemorrhage or hematoma (2.8%), and dyspareunia (1.5%). Four cases of cerebral ischemia were reported in this group. However, it is unclear whether this complication was due to a preexisting medical condition or was a result of the surgery itself. The reoperation rate for prolapse recurrence was highest (3.9%, range 0–29.1) in this group compared with the other two surgical groups. However, the total reoperation rate, including reoperations for complications as well as prolapse, was the lowest (5.8%, range 0–29.2).

The sacral colpopexy group included 5,639 patients from 52 studies, with mean follow-up of 26.5±20.1 months. Thirty-nine studies addressed sacral colpopexy by laparotomy, 10 laparoscopic sacral colpopexy, and three sacrohysteropexy. This group had the highest mean total complication rate of 17.1% (range 0–52.2). Similar to the traditional vaginal surgery group, the majority of complications were managed with pharmacologic intervention (5.8%) or no intervention (5.5%). Pain (2.3%), mesh erosion (2.2%), visceral injury (1.7%), and wound complica-

**Table 2. Weighted Averages and Confidence Intervals of Complications, Dindo Grades, Prolapse Reoperation Rates, and Total Reoperation Rates**

	Traditional Vaginal Repair*	Sacral Colpopexy	Mesh Kits
Number of studies <sup>†</sup>	48	52	24
Number of patients	7,827	5,639	3,425
Mean follow-up (mo±SD)	32.6±19.8	26.5±20.1	17.1±13.8
Dindo grade I	6.2 (5.7–6.7), 0–52.8	5.5 (4.9–6.1), 0–52.2	3.9 (3.3–4.6), 0–23.1
Dindo grade II	6.9 (6.4–7.6), 0–34.7	5.8 (5.2–6.4), 0–25.9	2.2 (1.7–2.7), 0–14.8
Dindo grade IIIa	0.2 (0.1–0.4), 0–2.1	1.0 (0.7–1.2), 0–8.3	1.3 (0.9–1.6), 0–12.7
Dindo grade IIIb	1.9 (1.7–2.3), 0–12.0	4.8 (4.2–5.4), 0–28.2	7.2 (6.3–8.0), 0–21.2
Dindo grade IVa, b	0.1 (0–0.1), 0–1.0	0.0 (0–0.07), 0.0	0.0 (0–0.1), 0.0
Dindo grade V	0.1 (0–0.1), 0–0.7	0.0 (0–0.07), 0.0	0.0 (0–0.1), 0.0
Mesh erosion or infection	0.5 (0.3–0.6), 0–20.0	2.2 (1.8–2.6), 0–28.2	5.8 (5–6.6), 0–21.2
Visceral injury <sup>‡</sup>	1.0 (0.8–1.3), 0–5.9	1.7 (1.3–2.0), 0–10.7	1.1 (0.7–1.4), 0–5.0
Cystotomy	0.4 (0.2–0.5), 0–5.9	1.0 (0.8–1.3), 0–10.7	0.7 (0.4–1.0), 0–4.3
Ureteral injury	0.3 (0.2–0.4), 0–3.5	0.2 (0.1–0.3), 0–1.6	0.1 (0–0.1), 0–1.0
Bowel injury	0.4 (0.3–0.5), 0–3.1	0.5 (0.3–0.7), 0–3.6	0.3 (0.1–0.5), 0–5.0
Pain <sup>§</sup>	1.6 (1.3–1.9), 0–38.9	2.3 (1.9–2.6), 0–25.0	2.5 (2.0–3.0), 0–23.1
Buttock pain	1.0 (0.8–1.3), 0–52.8	0.0 (0–0.07), 0–5.9	0.4 (0.2–0.7), 0–8.3
Dyspareunia	1.5 (1.2–1.8), 0–38.9	1.5 (1.1–1.8), 0–22.8	2.2 (1.7–2.7), 0–23.1
Fistula	0.1 (0–0.1), 0–1.5	0.0 (0–0.07), 0–0.8	0.2 (0.1–0.4), 0–4.2
Hemorrhage or hematoma	2.8 (2.5–3.3), 0–19.6	1.6 (1.3–1.9), 0–11.5	1.1 (0.7–1.4), 0–3.0
Wound complications <sup>  </sup>	0.5 (0.4–0.7), 0–10.8	1.5 (1.2–1.8), 0–16.8	0.2 (0–0.3), 0–7.5
Pelvic abscess	0.2 (0.1–0.3), 0–1.4	0.1 (0–0.2), 0–3.2	0.1 (0–0.2), 0–3.3
Lower extremity neuropathy	0.4 (0.3–0.6), 0–7.5	0.2 (0.1–0.3), 0–0.5	0.0 (0–0.1), 0.0
Urinary tract infection	3.5 (3.1–3.9), 0–34.8	2.1 (1.8–2.5), 0–25.9	0.8 (0.5–1.2), 0–14.8
Pulmonary embolism or deep vein thrombosis	0.1 (0.1–0.2), 0–2.2	0.3 (0.1–0.4), 0–3.2	0.0 (0–0.1), 0–1.4
Pulmonary complications	0.5 (0.4–0.7), 0–14.0	0.1 (0.1–0.4), 0–0.7	0.0 (0–0.1), 0.0
Cardiac complications	0.2 (0.1–0.3), 0–2.2	0.2 (0.1–0.3), 0–3.3	0.0 (0–0.1), 0.0
Total complication rate	15.3 (14.7–16.3), 0–52.8	17.1 (16.1–18.1), 0–52.2	14.5 (13.3–15.7), 0–23.1
Reoperation for prolapse recurrence	3.9 (3.5–4.4), 0–29.1	2.3 (1.9–2.7), 0–31.3	1.3 (1.0–1.7), 0–16.0
Total reoperation rate <sup>¶</sup>	5.8 (5.3–6.3), 0–29.2	7.1 (6.4–7.8), 0–26.2	8.5 (7.6–9.4), 0–30.0

SD, standard deviation.

Data are % (95% confidence interval), range unless otherwise specified.

\* Includes sacrospinous ligament suspension, uterosacral ligament suspension, iliococcygeus muscle suspension, and McCall's culdoplasty.

† Ten studies included multiple cohorts from different procedure groups.

‡ Includes cystotomy, ureteral injury, and bowel injury.

§ Includes buttock pain, dyspareunia, and unspecified pain.

|| Includes wound infections, vaginal cuff infections, and vaginal and abdominal wound dehiscences.

¶ Includes reoperations for complications (Dindo IIIb) and prolapse recurrence.

tions (1.5%) were the most common complications. There were 31 cases of dehiscence in the sacral colpopexy group compared with seven and four in the traditional vaginal surgery and mesh kit groups, respectively. Pulmonary emboli and deep vein thrombosis cases were reported more commonly after sacral colpopexy.

The vaginal mesh kit group included 3,425 patients from 24 studies, with a mean follow-up of 17.1±13.8 months. The mean total complication rate for this group was 14.5% (range 0–23.1). In contrast to the traditional vaginal surgery and sacral colpopexy groups, the majority of complications in this group required surgical intervention under general anesthesia (Dindo grade IIIb). Mesh erosion or infection was the most common complication (5.8%). Twenty-five

studies from all three groups, including four of the 24 studies in the vaginal mesh kit group, did not report how they managed these erosions, and it was assumed that 50% were managed in the operating room (Dindo IIIb).<sup>8–32</sup> Sensitivity analyses revealed no substantial effect on rates of reoperation for complications by varying this assumed proportion between 25% and 75%. Although fistulae were reported rarely (0.2%, range 0–4.2), the rate was highest for this group. Although pain-related complications were common in the sacral colpopexy group, dyspareunia rates were highest in the mesh kit group (2.2%, range 0–23.1). The reoperation rate for recurrent prolapse was lowest (1.3%, range 0–16.0) in the vaginal mesh kit group, although follow-up was shortest in this group. Additionally, the total reoperation rate was the highest



(8.5%, range 0–30.0) because of a higher rate of reoperations for complications such as mesh erosion.

## CONCLUSION

The findings of this meta-analysis demonstrate that total complication rates appear to be similar for traditional vaginal surgeries, sacral colpopexies, and vaginal mesh kits for the treatment of apical prolapse. However, despite having the shortest follow-up period out of the three groups, the reoperation rate for complications and total reoperation rate (including complications and prolapse recurrences) was highest in the vaginal mesh kit group. Most of these reoperations are necessitated by fistulae and mesh erosions. These complications are difficult to prevent, affect quality of life, and often are not managed medically. Although visceral injury and mesh erosion also led to reoperations in the sacral colpopexy and traditional vaginal surgery groups, the majority of all complications in these groups was managed pharmacologically. An additional key finding was that, despite the longer follow-up and greater number of participants, there was a lower total complication rate in the traditional vaginal surgery group compared with sacral colpopexy. The relatively higher rate of visceral injuries and wound complications in the sacral colpopexy group is likely attributed to the abdominal approach.

Our results are consistent with most past reviews of traditional vaginal surgeries and sacral colpopexy, and the few inconsistencies can be explained easily. Nygaard et al report the reoperation rate for prolapse recurrence after sacral colpopexy to be 4.4%, compared with our reoperation rate of 2.2%. Our meta-analysis included studies after 2004 and excluded more than 20 studies that were included in the review by Nygaard et al owing to sample size limitations or follow-up period. Mesh erosion rates were also higher (3.4%) in the study by Nygaard et al, likely for similar reasons.<sup>33</sup> In addition, the use of improved mesh quality such as synthetic monofilament materials may have decreased overall erosion rates.<sup>34</sup> Our results indicate a prolapse recurrence reoperation rate of 3.9% after traditional surgeries, with the majority of initial surgeries being sacrospinous ligament suspensions. Past reports have ranged up to 13%; the largest study of 243 patients reported a rate of 4.5%,<sup>35</sup> comparable with our current results. Similarly, reoperation rates for recurrence after uterosacral ligament suspension have ranged from 3% to 6.5% in large studies.<sup>36,37</sup> Olsen et al<sup>38</sup> report a reoperation rate for prolapse or incontinence repair of 29.2%. However, the study included reoperations after primary surgery

on the apical, anterior, and posterior compartments in addition to incontinence repairs.

The Dindo grading system<sup>7</sup> is a valid method to grade complications based on the invasiveness of the intervention. Although the use of this grading system is a strength of our study, it is not a perfect system because it is designed to be applied to different surgical procedures. Because the specifics of the intervention were not always stated by the authors, assumptions were made. These limitations were evident for complications requiring nonsurgical management (eg, lower extremity neuropathy and dyspareunia) where there was uncertainty regarding whether pharmacologic management was used (Dindo II) or not (Dindo I). This also was seen in cases of hemorrhage, where transfusion (Dindo II) or observation (Dindo I) usually was not indicated. To make comparisons between surgical procedures in the future, surgical trials should make attempts to list minor and severe complications and provide as much detail regarding any interventions needed to manage those complications.

Efforts were taken in this review to avoid reporting bias and publication bias by excluding studies that reported on only a specific complication rather than all complications. In addition, recent conference abstracts, most of which studied mesh kits, were included to further reduce a negative publication bias. We recognize that the use of abstracts may not have provided sufficient details of the study owing to word limitations. Furthermore, only the most morbid or most prevalent complications are mentioned in the abstract, with the remainder of the complications stated in the article. We elected to exclude studies with less than 3 months of follow-up because most prolapse reoperations would not have been diagnosed within this short time period.

There are several reasons that comparisons among the three surgical approaches should be interpreted with caution. First, very few randomized trials comparing these techniques are currently available. Of the 105 studies included in our analysis, only 4% represent clinical trials. Most of the studies included are retrospective case series of a single procedure without a comparison group. As such, the type of analysis we could perform is limited, and formal meta-analytic techniques could not be performed. Second, studies addressing traditional vaginal procedures and sacral colpopexy were likely better quality studies compared with studies on vaginal mesh kits, given the longer follow-up periods and larger sample sizes. The lowest rate of prolapse recurrence seen in the mesh kit group may be because the addition of



mesh improves objective anatomic cure, but it also may be a reflection of the follow-up period of 17.1 months, which is approximately half the follow-up period of the traditional procedures group. Future trials with longer follow-up ultimately will determine whether recurrence rates increase or remain unchanged. Third, given the variability of follow-up times among studies, time-to-event analyses would be ideal. However, because the timing of adverse events and reoperations often was not reported, these could not be performed. Finally, the number of patients enrolled and the number of patients lost to follow-up was not always indicated in every study.

An additional limitation was that most apical prolapse surgeries were performed with concomitant procedures. Procedures such as midurethral slings that use mesh can contribute to complications that may be difficult to discern from complications due to solely apical procedures. For example, there was a 0.5% mesh erosion rate in the traditional surgery group, although none of the procedures in this group involved the use of mesh.<sup>39,40</sup> Finally, because studies were grouped by the three approaches (traditional, sacral colpopexy, and mesh kits), comparisons cannot be made among procedures within a group. For example, conclusions cannot be drawn regarding which vaginal mesh device had the highest morbidity or which mesh material in the sacral colpopexy group led to the most mesh erosions.

In summary, there are no clinical trials or other comparative studies to date that compare these three main approaches to repairing the apical compartment in women undergoing surgery for pelvic organ prolapse. In this meta-analysis, we attempted to summarize the available observational studies to provide some guidelines on the relative complication and reoperation rates of these approaches. Sacral colpopexy is considered by some the gold standard apical suspension procedure.<sup>4</sup> In support of this, sacral colpopexy had a relatively low rate of reoperation for prolapse recurrence. However, this was at the expense of a high complication rate. Traditional vaginal procedures, in contrast, had a higher rate of reoperation for prolapse recurrence but fewer complications that required surgical intervention. Most importantly, our results suggest that, despite the lowest reoperation rate for prolapse recurrence, vaginal mesh kits have the highest rate of complications that require surgical intervention, which, on balance, results in the highest rate of total reoperation after apical suspension for pelvic organ prolapse. This raises the concern that the risks of these newer procedures may be greater than their benefits. One can speculate that

more recurrences and complications may be diagnosed with time, given the relatively shorter mean follow-up period in the mesh kit group. On the other hand, this may reflect the “learning curve” of this recently adopted new technology. More long-term studies on vaginal mesh kits and clinical trials that directly compare these surgical techniques are needed to support these findings definitively.

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# EXHIBIT E

1 UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT WEST VIRGINIA  
2 CHARLESTON DIVISION  
3 ) Master File  
IN RE: ETHICON, INC., ) No. 2:12-CV-02327  
4 PELVIC REPAIR SYSTEM ) MDL No. 2327  
PRODUCTS LIABILITY )  
5 LITIGATION ) JOSEPH R. GOODWIN  
\_\_\_\_\_ ) U.S. DISTRICT JUDGE  
6 ) \_\_\_\_\_  
THIS DOCUMENT RELATES TO )  
7 PLAINTIFFS: ) CASE NO. 2:12-CV-02099  
 )  
8 Tina Wilson, et al v. )  
Ethicon, Inc., et al )

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10 \*\*\*\*\*  
11 ORAL DEPOSITION OF  
12 CHRISTINA PRAMUDJI, M.D.  
13 JULY 7, 2016  
14 \*\*\*\*\*  
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<p style="text-align: right;">Page 74</p> <p>1 Obviously, we know you've read the literature  2 on TVT. Does that literature speak to -- and I'm  3 talking medical studies -- speak to the effect, if  4 any, positive, negative, of TVT on quality of life, on  5 emotional health, on relationships, on sexual function  6 or dysfunction?</p> <p>7 MR. THOMPSON: Object to form.</p> <p>8 A. Yes, it does.</p> <p>9 Q. (By Mr. Snell) Is that -- is it your reading  10 of that literature and knowledge base on those areas  11 pertaining to psychiatric history and emotional health  12 something that is part of your, you know, knowledge  13 base?</p> <p>14 MR. THOMPSON: Object to form.</p> <p>15 A. Yes, I know that the literature and, of  16 course, my own experience with the TVT is that it  17 improves the quality of life of patients tremendously.</p> <p>18 Q. (By Mr. Snell) And do you in your general  19 report identify studies and data supporting your  20 opinions about its effect on quality of life,  21 emotional health and things of that nature?</p> <p>22 MR. THOMPSON: Object to form.</p> <p>23 A. Yes.</p> <p>24 Q. (By Mr. Snell) In assessing TVT and its</p>	<p style="text-align: right;">Page 76</p> <p>1 emotional health one of the things assessed following  2 treatment with TVT?</p> <p>3 A. Yes, No. 6 is emotional health, nervousness,  4 depression, et cetera.</p> <p>5 Q. And so is it correct or not that in your  6 field assessing emotional health is actually part and  7 parcel of what you do in patients who receive TVT in  8 assessing not just that one aspect, but their overall  9 outcome?</p> <p>10 MR. THOMPSON: Object to form.</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. (By Mr. Snell) You were shown -- you were  13 shown the IFU and asked if it contained certain words,  14 a warning of certain words pertaining to erosion. Do  15 you recollect that?</p> <p>16 A. Yes.</p> <p>17 Q. And I'm just going to ask you about the  18 bladder erosion issue since -- Counsel, and we  19 discussed and the other areas weren't really gone  20 into, so I'm just going to stick with the erosion.</p> <p>21 On the very first page in the section titled  22 Important, does this IFU for TVT state it is not a  23 comprehensive reference to surgical technique for  24 correcting SUI, device should be used by physicians</p>
<p style="text-align: right;">Page 75</p> <p>1 impact, in your opinion, it's positive, positive  2 effects on quality of life, emotional health,  3 relationships, et cetera. Do scientists and surgeons  4 like yourself use standardized questionnaires to  5 assess the impact on TVT on those various domains?</p> <p>6 MR. THOMPSON: Object to form.</p> <p>7 A. Yes, we do.</p> <p>8 Q. (By Mr. Snell) For example, I was just  9 looking -- one of the papers you cite to of many in  10 your general report is the Laura Kenyan 2014  11 randomized control trial that looked at TVT. Do you  12 recall that?</p> <p>13 A. Yes.</p> <p>14 Q. And they did, according to your report,  15 numerous questionnaires that show significant  16 improvements on quality of life, satisfaction, things  17 of that nature. Do you recollect that?</p> <p>18 MR. THOMPSON: Object to form.</p> <p>19 A. Yes.</p> <p>20 Q. (By Mr. Snell) And one of those  21 questionnaires, for example, was the incontinence  22 impact questionnaire 7. And I don't have the ability  23 to print out a copy, but I will represent and I will  24 show you and Counsel. Of the seven questions, is</p>	<p style="text-align: right;">Page 77</p> <p>1 trained in the surgical treatment of stress urinary  2 incontinence and specifically implanting the TVT  3 device?</p> <p>4 A. Yes, that's what it says.</p> <p>5 Q. Okay. And would the risk of bladder  6 perforation and bladder erosion, is that a risk that  7 would be commonly known to the intended user, the  8 physician trained in stress urinary incontinence and  9 TVT?</p> <p>10 MR. THOMPSON: Object to form.</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. (By Mr. Snell) And when it states that the  13 surgeon should specifically be trained in implanting  14 TVT, if the surgeon undergoes that training, would he  15 or she be made aware of the risk of bladder  16 perforation or bladder erosion?</p> <p>17 MR. THOMPSON: Object to form.</p> <p>18 A. Yes.</p> <p>19 Q. (By Mr. Snell) Should the pelvic floor -- is  20 the pelvic floor surgeon the intended user of the TVT  21 device?</p> <p>22 A. Yes.</p> <p>23 Q. Would that intended user be expected to know  24 of the risk of bladder perforation and bladder erosion</p>

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1 when using instruments passing by the bladder placing  
2 a sling?  
3 MR. THOMPSON: Object to form.  
4 A. Yes.  
5 Q. (By Mr. Snell) And you mentioned that that's  
6 would be the literature and that can happen with  
7 autologous slings. Is that what you were referencing?  
8 MR. THOMPSON: Object.  
9 A. Yes.  
10 Q. (By Mr. Snell) Is your surgical training and  
11 residency learning to do sling procedures, whether  
12 synthetic or autologous or something else, is that  
13 elemental risk that you learn about in your basic  
14 training?  
15 MR. THOMPSON: Object to form.  
16 A. Yes, it is.  
17 Q. (By Mr. Snell) Is that one of the reasons  
18 why you believe that that would be a commonly known  
19 risk to the intended user?  
20 MR. THOMPSON: Object to form.  
21 A. Yes.  
22 Q. (By Mr. Snell) Under Instructions for Use,  
23 we didn't really talk about this, but actually, I want  
24 to go through some of this. It talks about the guide

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1 and it says the purpose of the guide is to move the  
2 bladder neck and urethra away from where the tip of  
3 the needle will pass into the retropubic space. It  
4 also says when you're using the guide you move the  
5 bladder contralaterally to the side of the needle  
6 passage. Do you see that?  
7 A. Yes.  
8 Q. It also says cystoscopy is performed to  
9 confirm bladder integrity. Do you see that?  
10 A. Yes.  
11 Q. Do those three statements warn a pelvic floor  
12 surgeon that, hey, there is a risk of bladder  
13 perforation and bladder erosion?  
14 MR. THOMPSON: Object to form.  
15 A. Yes.  
16 Q. (By Mr. Snell) When they talk about  
17 confirming bladder integrity, what are they talking  
18 about?  
19 A. They're talking about confirming that the  
20 trocar did not traverse through the bladder, that the  
21 sling is not going through the bladder wall.  
22 Q. If the sling is in the bladder wall, what is  
23 that?  
24 A. That's a perforation. It's a potential

Page 80

1 erosion.  
2 Q. And would that be understandable to the  
3 intended user, a pelvic floor surgeon like yourself?  
4 MR. THOMPSON: Object to form.  
5 A. Yes.  
6 Q. (By Mr. Snell) Is the intention on using the  
7 guide, moving the bladder contralaterally, doing  
8 cystoscopy, do those have -- are those done for a  
9 reason?  
10 A. Yes. Those are done to confirm that the  
11 sling is not going through the bladder or too close to  
12 the bladder mucosa. And that's implanted in the  
13 bladder wall. It should be outside the bladder wall.  
14 Q. Are those done to reduce the risk of  
15 perforation and ultimately bladder erosion?  
16 MR. THOMPSON: Object to form.  
17 A. Yes.  
18 Q. (By Mr. Snell) Would that be understandable  
19 to a pelvic floor surgeon who is trained on stress  
20 urinary incontinence surgery trained on the TVT  
21 device?  
22 MR. THOMPSON: Object to form.  
23 A. Yes.  
24 Q. (By Mr. Snell) Under Warnings and

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1 Precautions it says: User should be familiar with  
2 surgical technique for bladder neck suspensions.  
3 Does that include the autologous slings that  
4 you referenced earlier?  
5 A. Yes, it does.  
6 Q. Where there is a known risk of bladder  
7 perforation and bladder erosion with those procedures?  
8 A. Yes, it does.  
9 Q. So a surgeon coming in to use a TVT, if he or  
10 she was familiar with surgical technique of bladder  
11 neck suspensions, would he or she, by way of their  
12 basic training and knowledge, be aware of the risk of  
13 bladder perforation and erosion?  
14 MR. THOMPSON: Object to form.  
15 A. Yes, they would.  
16 Q. (By Mr. Snell) And he also goes to state  
17 that those surgeons should be adequately trained in  
18 implanting the TVT before employing the TVT.  
19 Does training on the TVT warn and inform  
20 surgeons about the risk of bladder perforation and  
21 erosion?  
22 MR. THOMPSON: Object to form.  
23 A. Yes, it does.  
24 Q. (By Mr. Snell) And did you, yourself,

<p style="text-align: right;">Page 82</p> <p>1 perform professional education training on the TVT  2 systems?  3 A. Yes, I did.  4 Q. It says: The TVT procedure should be  5 performed with care to avoid the bladder. Attention  6 to local anatomy and proper passage of needles will  7 minimize risks.  8 What kind of risks are they talking about  9 there that you would understand as a pelvic floor  10 surgeon?  11 MR. THOMPSON: Object to form.  12 A. They're talking about bladder mesh erosion.  13 Q. (By Mr. Snell) Cystoscopy should be  14 performed to confirm bladder integrity or recognize a  15 bladder perforation.  16 Did I read that correctly?  17 A. Yes, you did.  18 Q. Does that warn a surgeon, a pelvic floor  19 surgeon, about the risk of perforation or erosion?  20 MR. THOMPSON: Object to form.  21 A. Yes, it does.  22 Q. (By Mr. Snell) And you point out also under  23 Adverse Reactions, it actually has the word "erosion."  24 MR. THOMPSON: Object the form.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. (By Mr. Snell) And, for example, you cite  2 systematic reviews, which you've testified before, the  3 highest level of evidence. Those systematic reviews  4 for the retropubic TVT or the sling report rates of  5 dyspareunia at zero percent or sexual dysfunction is  6 zero percent. Do you recall putting that in your  7 general report?  8 MR. THOMPSON: Object to form.  9 A. Yes.  10 Q. (By Mr. Snell) Is that a basis for your  11 opinion that TVT did not cause the Plaintiff's  12 dyspareunia in this case?  13 A. Yes.  14 MR. THOMPSON: Object to form.  15 Q. (By Mr. Snell) And actually, compared to the  16 pubovaginal slings that Plaintiff's counsel asked you  17 about, is the risk of pain and sexual dysfunction with  18 TVT -- how does take compare?  19 A. It's actually less.  20 Q. And in your report where you talk about  21 reliable literature documenting significant  22 improvements in sexual function, is that a basis for  23 your opinions in this specific case?  24 MR. THOMPSON: Object to form.</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. (By Mr. Snell) Is that correct?  2 A. Yes, that's correct.  3 Q. Is the TVT IFU adequate to warn a pelvic  4 floor surgeon of the risk of bladder perforation and  5 bladder erosion, in your opinion?  6 MR. THOMPSON: Object to form.  7 A. Yes, it is.  8 Q. (By Mr. Snell) Does it actually, in numerous  9 places, actually warn about those risks?  10 MR. THOMPSON: Object to form.  11 A. Yes, it does.  12 Q. (By Mr. Snell) You were asked questions  13 about your opinion that the TVT does not -- did not  14 contribute to Ms. Wilson's dyspareunia. As support  15 for your opinion, I note in your case-specific report  16 that you incorporate your TVT general report. Is that  17 correct?  18 A. Yes.  19 Q. And so the literature and data and things at  20 Page 51, 52, 53, pertaining to TVT and its effect and  21 risk, if any, for dyspareunia, do you incorporate  22 those bases?  23 MR. THOMPSON: Object to form.  24 A. Yes.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Yes.  2 Q. (By Mr. Snell) On the topic of urge  3 incontinence, the urgency, overactive bladder, is that  4 a topic you also cover in your general report?  5 A. Yes, it is.  6 Q. And for reference, I'm going to point to  7 Pages 49 through 51, for example. Is that -- does  8 that part of your general report talk about urgency,  9 overactive bladder, urge incontinence, and whether TVT  10 has been demonstrated to be a cause of those factors?  11 A. Yes, it --  12 MR. THOMPSON: Object to form.  13 A. Yes, it does.  14 Q. (By Mr. Snell) You identify various factors  15 in Mrs. Wilson's case that you believe contributed to  16 her urgency and urge incontinence. Let me ask you  17 this: In your report at Page 49, general report, you  18 talk about mixed urinary incontinence. Can you tell  19 us what that is very briefly?  20 A. Yes, that's where the patient has two kinds  21 of incontinence. One is stress incontinence with  22 coughing, sneezing, exercise. And the second is the  23 urge incontinence where they have the feeling that  24 they've gotta go, gotta go. And so if they have both</p>

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ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do  
hereby certify that I have read the  
foregoing pages, and that the same is  
a correct transcription of the answers  
given by me to the questions therein  
propounded, except for the corrections or  
changes in form or substance, if any,  
noted in the attached Errata Sheet.

\_\_\_\_\_  
CHRISTINA PRAMUDJI, M.D. DATE

Subscribed and sworn  
to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

My commission expires: \_\_\_\_\_

\_\_\_\_\_  
Notary Public

Page 91

THE STATE OF TEXAS:  
COUNTY OF FT. BEND:

I, Tamara Vinson, a Certified Shorthand  
Reporter and Notary Public in and for the State of  
Texas, do hereby certify that the facts as stated by  
me in the caption hereto are true; that the above and  
foregoing answers of the witness, CHRISTINA PRAMUDJI,  
M.D., to the interrogatories as indicated were made  
before me by the said witness after being first duly  
sworn to testify the truth, and same were reduced to  
typewriting under my direction; that the above and  
foregoing deposition as set forth in typewriting is a  
full, true, and correct transcript of the proceedings  
had at the time of taking of said deposition.

I further certify that I am not, in any  
capacity, a regular employee of the party in whose  
behalf this deposition is taken, nor in the regular  
employ of his attorney; and I certify that I am not  
interested in the cause, nor of kin or counsel to  
either of the parties.

GIVEN UNDER MY HAND AND SEAL OF OFFICE, on  
this, the \_\_\_\_ day of July, 2016.

\_\_\_\_\_  
Tamara Vinson, Texas CSR No. 3015  
Expiration Date: 12-31-2016

GOLKOW TECHNOLOGIES, INC.  
Texas CRCB Registration #690  
440 Louisiana, Suite 910  
Houston, Texas 77002  
www.golkow.com

# EXHIBIT F

# **Christina Pramudji**

## **Supplemental Reliance List *in Addition to Materials Referenced in Report***

**Mary Shelton**

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Description
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**Production Materials**

<b>Document Description [Bates Range]</b>
2000 June TVT Surgeons Resource Monograph
2005 Prolift Prof Ed Slide deck (P's Exhibit 127)
2005-2006 Gynecare Prolift Pelvic Floor Repair Systems – slides (16 pages)
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2007 & 2008 Gynecare Prolift Pelvic Floor Repair Systems – slides (46 pgs)
2007 Prolift Prof Ed Slide deck (P's Exhibit 128)
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
9.22.2011 Letter to surgeons
A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse by V. Lucente, et al. 1 pg
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
Australian Pelvic Floor Discussion
Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul dated 6/21/2012
Brigitte Fatton Powerpoint Presentation entitled "Complications in Pelvic Floor Dysfunction Surgery: evaluation and management.
Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2005 (8 pgs)
Brochure Treatment Options for Pelvic Organ Prolapse Stop coping. Start living. Dated in 2008 Gynecare Prolift (15 pgs)
Classification Website Intro "An International Urogynecological Association (IUGA/Internation Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertionm of Prostheses (Meshes, Implants, Tapes) & Grafts in Female Pelvic Floor Surgery."
Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013
Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.
D00001256-2005 Prolift Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems) [Native Format]
D00001260-2007 and 2008 Prolift and M Prof Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems)[Native Format]
Dear Surgeon Letter from Piet Hinoul and Aaron Kirkemo.
Declaration of Reynaldo Librojo in Support of Motion for Summary
Declaration of Thomas A. Barbolt, Ph.D., DABT, 1981-2011 in Support of Motion for Summary Judgement
DEFT 19.1-19.6 - Prolift M IFU
DEFT 730.1-730.72 - 2007 Prolift Surgeons Monograph
DEPO.ETH.MESH.00004755 - Guidoin Explant
Document entitled "Delay in Prosima Activities"
Document entitled "Pelvic Floor Repair. Extended Review of Medical Literature."
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2

**Production Materials**

Email string re - Revised write up of the DeLeval and Waltregny visit
Email string re: Ultrapro vs Prolene Soft Mesh
Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled :Vaginal repair with mesh no better than colporrhapy for pelvic organ prolapse.
ETH MESH 00082651-54
ETH MESH 07903682-83
ETH MESH 08307644-45 - Piet Hinoul_s email and Excel attachment with 104 RCTs attached to email
ETH MESH 09268043-45
ETH.MESH. 00484929 - 2007 & 2008 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH..07462313 - Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response
ETH.MESH.00000172 - 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call
ETH.MESH.00000173 - 8/25/11 Registration list for 8/25/11 call
ETH.MESH.00001595-1606 - Reisenauer, C. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. European Journal of Obstetrics & Gynecology and Reproductive Biology 2006
ETH.MESH.00003895 - Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee
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ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review. Journal of Urology 2006; 175: 439-446
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00019117-21 - Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.
ETH.MESH.00020763 - Prolift +M Profession Education Slide Deck
ETH.MESH.00020764 - Prolift +M Profession Education Slide Deck
ETH.MESH.00031323 - Memo to Customer from Sean M. O'Bryan dated 2.8.05 regarding Gynecare Prolift
ETH.MESH.00031324-25 - Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair
ETH.MESH.00064002-04 - Email string, top one from Judith Gauld to Scott Jones re: US preceptors for Prosima.
ETH.MESH.00064054 - Gynecare Prosima™ Pelvic Floor Repair System - Global Launch Strategy

**Production Materials**

ETH.MESH.00064138-39 - Document entitled "PROSIMA Critical Success Factors."
ETH.MESH.00071755 - Prosimas - Apical Support Learning Guide
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00076167 - Letter from Bryan Lisa to Dan Smith re: Prosimas Product Release Authorization; cc: Stephanie Kute, Jennifer Paine.
ETH.MESH.00076710-90 - Clinical Study Report. Evaluation of Prosimas for Pelvic Organ Prolapse. Protocol Number: 300-06-005. "A Prospective, Multi-centre Study to Evaluate the Clinical Performance of Gynecare Prosimas Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse."
ETH.MESH.00077073-093
ETH.MESH.00077094-111
ETH.MESH.00077395
ETH.MESH.00078114-15 - Memo to Prosimas Regulatory File. Minutes from Teleconference with FDA for Prosimas 510(k).
ETH.MESH.00081288-89 - Memo to Jennifer Paine, et al from Renee Selman dated 1.16.08 regarding Project Lightning Status
ETH.MESH.00082651-54 - Email string, top one from Marcus Carey to J. Meek, D. Robinson, P. Hinoul,et al. re: Technical feedback on Prosimas.
ETH.MESH.00083812-3814
ETH.MESH.00086463-65 - E-mail from Piet Hinoul to Zeb Viana, et al. regarding TR: PROSIMAS TAKE AWAY MESSAGES; cc: Bart Pattysen, et al.
ETH.MESH.00093526-44 - Prolift +M Profession Education Slide Deck
ETH.MESH.00093991 - Prolift +M Profession Education Slide Deck
ETH.MESH.00108120-21 - Email string, top one from Douglas Grier to Lissette Caro-Rosado, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattysen.
ETH.MESH.00125373 - Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.
ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input
ETH.MESH.00127103 - Email from Greg prine to Scott Jones, Jonathan Meek re: Prosimas Road Show; cc: Lesley Fronio and Kevin Mahar.
ETH.MESH.00127125-26 - Email From Lewis to Mahar, et al. re: How did Dr. Grier's Prosimas cases go?
ETH.MESH.00129102 - Suggested Remarks - Incontinence and Pelvic Floor Summit What a Difference a Decade Makes
ETH.MESH.0013114-51 - Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosimas Global Launch Team.
ETH.MESH.00144449 - Letter from David Robinson re: decision to delay preceptor training activities for Prosimas (not signed).
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104-10 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.

**Production Materials**

ETH.MESH.00281482-84
ETH.MESH.00295355 - 2010 TVT Exact Prof Ed
ETH.MESH.00303310-13 - Memo from Dan Lamont to Gynecare Prosima Risk Management Report (RMR-0000029) re: Pelvic Floor Product(s) Complaint Review for Gyneacre Prosima Risk Management.
ETH.MESH.00310205 - Product Quality Issue re: Prosima signed by Mark Yale.
ETH.MESH.00310206 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).
ETH.MESH.00316849-50
ETH.MESH.00318930 - (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00318934 - Document entitled " Delay in Prosima Activities."
ETH.MESH.00329474-509 - Project Mint Design Review
ETH.MESH.00335084-85 - Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.
ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.00369995 - 2008 TVT Family of Products
ETH.MESH.00370315 - Prosima Training Deck 1
ETH.MESH.00371595-903 - Prosima 510(k) and Clearance letter
ETH.MESH.00372564-68 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number 2003-016
ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
ETH.MESH.00373310-88 - 2003 TVT Support for Incontinence General Prof Ed Deck
ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL June 22, 2001
ETH.MESH.00397674 - 2002 Dr. Miklos Minimizing and Managing TVT Complications
ETH.MESH.00405513-514
ETH.MESH.00409158 - (Official) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00418855-56 - Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.
ETH.MESH.00424374-75 - Email string, top one from Jonanthan Fernandez ro Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.
ETH.MESH.00426441 - Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.
ETH.MESH.00442129 - PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer
ETH.MESH.00455676-77 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.
ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force

**Production Materials**

ETH.MESH.00467320 - Email string, top one from Andrew Meek to Bart Pattyson, Paul Parisi re: November Lab.
ETH.MESH.00484929 - 2005-2006 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.00495796-98 - Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.
ETH.MESH.00510562-63 - Email string, top one from Kevin Frost to DL-ETHUSSO EWHU DMs, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.
ETH.MESH.00516424-27
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00541708-09 - Document entitled "Notes from Competitive Ad Board."
ETH.MESH.00541873 - Chart listing Proposed Lab Scheduling for August 4th.
ETH.MESH.00541876-78 - Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.
ETH.MESH.00542347-48 - Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.
ETH.MESH.00542463 - Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: 2-Year Clinical Data
ETH.MESH.00547021 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.00547036-37 - Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.
ETH.MESH.00547500-01 - Email re: 69% Success
ETH.MESH.00573815 - Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima* Pelvic Floor Repair System) June 2010.
ETH.MESH.00573860-78 - (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolpase with Tension-free Mesh and Vaginal Support Device."
ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00575580-81 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.
ETH.MESH.00575634-35 - ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."
ETH.MESH.00578081-83 - Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.
ETH.MESH.00578550 - (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."
ETH.MESH.00579296 - Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolpase Patients.
ETH.MESH.00580588-89 - Email string dated 3/25/2010, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch
ETH.MESH.00580711-13 - Email re: Piet explains PS in Prosima
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT

**Production Materials**

ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00591563-65 - Email re: Smelly VSDs
ETH.MESH.00592224-29 - E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima
ETH.MESH.00592585-87 - Email re: No RCT for Prosima
ETH.MESH.00594266 - Email re: Overstating Success - Less Misleading
ETH.MESH.00594455 - Email re: Stop communicating over email
ETH.MESH.00594528 - Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.
ETH.MESH.00595468-70 - Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.
ETH.MESH.00595889-90 - Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.
ETH.MESH.00604183-86 - Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.
ETH.MESH.00631782-84 - FDA Letter re: K063562 Gynecare Prosima
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00662233 - Email from Scott Jones to DL-Ethusso dated 12/15/2009 re: PAGS Leads
ETH.MESH.00679637-40 - Email string, top one from Zenobia Walji to Ron Naughton, et al. re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00759327-35 - Document entitled "Experience what's new in incontinence and pelvic floor repair." 2010 ICS IUGA Executive Agenda
ETH.MESH.00800521-22 - Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.
ETH.MESH.00806974-75 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.00807570 - Revised Chart listing Proposed Lab Schedule
ETH.MESH.00807772-74 - Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.
ETH.MESH.00807972-73 - Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.00808121-22 - Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.
ETH.MESH.00817181 - Email dated 1/22/2010 from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.
ETH.MESH.00820634 - Invitation to participate in Gynecare Prosima Virtual Round Table
ETH.MESH.00832749-54 - Risk Management Report: Prosima Pelvic Floor Repair Kit
ETH.MESH.00833948-49 - Email from David Robinson to Jessica Shen re: Prosima Study.
ETH.MESH.00834910-11 - Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.
ETH.MESH.00840886-87 - Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.
ETH.MESH.00843043 - Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.

**Production Materials**

ETH.MESH.00849014-17
ETH.MESH.00850335-36 - Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.
ETH.MESH.00851319-21 - E-mail string dated 1/21/2010, top one from Piet Hinoul to Clifford Volpe and David Robinson re: dimensions of the PROSIMA implant
ETH.MESH.00851319-321 - Email string, top one from P. Hinoul to C. Volpe, et al. re: Prosima implant dimensions.
ETH.MESH.00856579-82 - E-mail string dated 11/3/2010 re: neo clinical trial. Piet Hinoul: "Each individual study does not contribute to the success of those products
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00860239-310 - TVT-O IFU
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.00895089-91 - Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.
ETH.MESH.00921692-94 - Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.
ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement
ETH.MESH.00925065-67 - Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.
ETH.MESH.00991195-257 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number CT-TVM-001-03
ETH.MESH.00993273 - 2006 TVT-O Summit Presentation by Raders and Lucente
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.01075187-215 - Clinical Expert Report Gynecare Prolift Pelvic Floor Repair System dated 7.2.10
ETH.MESH.01136239-40 - Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.
ETH.MESH.01154031-37 - Clinical Expert Report - Gynemesh Prolene Soft
ETH.MESH.01198058 - (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."
ETH.MESH.01200286 - Powerpoint: Gynecare Prosima : Overview.
ETH.MESH.01201973 - Propsed Lab Schedule (2nd Revision)
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01228079-84 - Nilsson Podcast Transcript

**Production Materials**

ETH.MESH.01237077-79 - Email dated 9/3/2009 from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01244824-26 - Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.
ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009
ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.01310817-29 - Ethicon Biocompatibility Risk Assessment for Gynecare Prolift Total Pelvice Floor Repair System dated 1.19.05
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01320328-33 - Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
ETH.MESH.01320351-67 - Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006
ETH.MESH.01411037-39 - Summary re: Project Mint
ETH.MESH.0141137-39 - Document re: summary of changes in mesh implant from Project Mint to final production.
ETH.MESH.01428106-112 - Carvigni, M. The use of synthetics in the treatment of pelvic organ prolapse. Curr Opin Urol 2001; 11: 429-435.
ETH.MESH.01593930-42 - Prosima Clinical Expert Report (not signed or dated).
ETH.MESH.01595614-753 - Prolift +M IFU
ETH.MESH.01612323-33 - Patient Brochure: Pelvic Organ Prolapse "Get the Facts, Be Informed, Make Your Best Decision."
ETH.MESH.01638150 - Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System Backrgound; Halina Zyczynski, M.D.
ETH.MESH.01678340 - Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.
ETH.MESH.01707963 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.01708116-17 - Email string, top one from Bart Pattyson to Georgia Long re: TVT Abbrevio and Prosima training; cc: Elizabeth Kolb, Andrew Meek.
ETH.MESH.01708180 - Chart listing financial information re: preceptors.
ETH.MESH.01708190 - Chart listing financial information re: preceptors.
ETH.MESH.01730626-29 - Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.
ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5
ETH.MESH.01752532-535 - Mesh design argumentation issues
ETH.MESH.01776504-10 - Email re: 60% Success
ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.
ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Lucente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh

**Production Materials**

ETH.MESH.01785259-260 - Email dated 1/17/2010 from Dr. Piet Hinoul to Dr. David Robinson, et al. Re: +M relaxation
ETH.MESH.01803816-18 - Summary re: Project Mint
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01821586-87 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Dan Smith, et al.
ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)
ETH.MESH.02001398-473 - Prolift IFU
ETH.MESH.02010349-62 - Prosima Clinical Expert Report signed by David Robinson
ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.02066770-71
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02105765-771 - FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence issued 10.20.08; Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08
ETH.MESH.02114615-16 - Email string, top one from Libby Lewis to Donna Abely, et al. re: Remaining 2010 labs.
ETH.MESH.02156379-80
ETH.MESH.02211890 - Test Report
ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.
ETH.MESH.02215374-375 - Jacquetin B. Prolene Soft (Gynecare) Mesh for Pelvic Organ Prolapse Surgical Treatment: A Prospective Study of 264 Patients. Abstract 767
ETH.MESH.02215565-567 - Email from Scott Ciarrocca to multiple recipients re: a message from Barbara Schwartz re: Prolift (01.02.2005).
ETH.MESH.02217343-44
ETH.MESH.02229013 - Email re: IFU errors
ETH.MESH.02229051 - Video: "Biomechanics"
ETH.MESH.02229054 - Video: "What to Expect"
ETH.MESH.02229055 - Video: "VSD Case Series 1"
ETH.MESH.02232685 - Marketing: "Your Proof: Her dance class."
ETH.MESH.02232773-801 - Prolift +M Profession Education Slide Deck
ETH.MESH.02232854-74 - Prolift +M Profession Education Slide Deck
ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion
ETH.MESH.02233126-187 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233126-187 - Prolift+M Educational Module
ETH.MESH.02233290 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233410 - US Launch - Premarket Preparation (PMP) 2009 US Sales Meeting Brief

**Production Materials**

ETH.MESH.02233417 - Prosima New Product Request Form
ETH.MESH.02233418-38 - Prosima - Surgical Technique
ETH.MESH.02233439-51 - US Training 1-year clinical data: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.
ETH.MESH.02233452-67 - Prosima - US Training - Background and Development History
ETH.MESH.02233539 - Prosima - New Product Request Form
ETH.MESH.02233540 - Prosima - 2009 Sales Training Program
ETH.MESH.02233605 - (B&W) Webinar Invite "The treatment of Symptomatic Moderate Pelvic Organ Prolapse."
ETH.MESH.02233640 - (B&W) Prosima - Module 4: 2-Year Clinical Data
ETH.MESH.02233651-73 - One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device. Results from the International Multicenter Gynecare Prosima™ Study.
ETH.MESH.02233674-92 - (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"
ETH.MESH.02233699-710 - Prosima - An Interview with Dr. Marcus P. Carey.
ETH.MESH.02233713 - Objective Success Rate Learning Guide
ETH.MESH.02233726-27 - Prosima Product Page on Ethicon-360 12.09
ETH.MESH.02233728 - (native) Gynecare Prosima™ Key Procedural Steps
ETH.MESH.02233834 - (B&W) 2009 Sales Aid Guide
ETH.MESH.02233840 - MRI Flashcard "Prosimia - The first fixationless mesh system that maintains anatomical position."
ETH.MESH.02233842 - Virtual Round Table Registration Form 9.2010
ETH.MESH.02233843-49 - Clinical Study Findings Discussion for Gynecare Prosima™ by Piet Hinoul (Audio Transcript).
ETH.MESH.02233851-51 - Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."
ETH.MESH.02233857-59 - AJOG Press Release (Draft)
ETH.MESH.02233862-80 - AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.
ETH.MESH.02233881-88 - Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.
ETH.MESH.02233961 - Virtual Round Table Follow-up Letter.
ETH.MESH.02233962 - Virtual Round Table Follow-up Letter.
ETH.MESH.02233963 - Virtual Round Table Invitation 9.2010
ETH.MESH.02233964 - (B&W) Prosima DVD
ETH.MESH.02234001-02 - (Marketing) The Gynecare Prosima™ Pelvic Floor Repair System Story
ETH.MESH.02234005-171 - Prosima Sales Training Program
ETH.MESH.02234173-77 - Prosima Messaging practice Coaching Check List
ETH.MESH.02237107-15 Introducing Gynecare Prosima for Ethicon Epiphany 247.
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser/Ultrasonic) Mesh Particle loss less than 2 percent for both
ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.
ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.
ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.

**Production Materials**

ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU
ETH.MESH.02293981 - Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Response
ETH.MESH.02318553-54 - Gynecare Prosima™ Combined Pelvic Floor Repair System Clinical Strategy.
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02322037-39 - Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial.
ETH.MESH.02330766 - TVT-O (Reproducible Vaginal Approach) (TVTO-384-10-8-12)Production 36_000124_4580875_d
ETH.MESH.02340306-69 - TVT IFU
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340471-503 - TVT IFU
ETH.MESH.02340504-67 - TVT IFU
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340756-828 - TVT-O IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02340829-901 - TVT-O IFU
ETH.MESH.02340902-73 - TVT-O IFU
ETH.MESH.02340974-1046 - TVT-O IFU
ETH.MESH.02341203-13 - TVT Abbrevio IFU
ETH.MESH.02341398-410 - Prosima IFU (6.18.10 to discontinuance) - English only 13 pages
ETH.MESH.02341398-453 - Prosima IFU
ETH.MESH.02341398-453 - Prosima IFU
ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341454-521 - Prolift IFU
ETH.MESH.02341522-527 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341522-89 - Prolift IFU
ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341658-733 - Prolift IFU
ETH.MESH.02341734-809 - Prolift IFU
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02579701-06 - Email re: Piet re Problem with posterior inserter
ETH.MESH.02596085 - Letters to the Editor 2010; 1457
ETH.MESH.02597949-50 - Hinoul, P., et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine."
ETH.MESH.02599918-20 - Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosima Data Conference Call.
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02614610-624 - Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
ETH.MESH.02615519-658 - Prolift +M IFU

**Production Materials**

ETH.MESH.02658316 - Cover Letter
ETH.MESH.02658317-352 - Postmarket Surveillance Study No. PS120043; Gynecare Prolift +M Pelvic Floor Repair Systems; Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.02967410-12 - Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.
ETH.MESH.03048942 - Document entitled "New" Mint January 05, 2006.
ETH.MESH.03049774-75 - Gynecare Prosima* Combined Pelvic Floor Repair System: Clinical Strategy.
ETH.MESH.03056578-80 - Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima* investigator bulletin.
ETH.MESH.03109341 - Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.
ETH.MESH.03160821 - Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.
ETH.MESH.03160822-23 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.03160827-28 - Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.
ETH.MESH.03162936-38 - Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.
ETH.MESH.03393725-31 - Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract
ETH.MESH.03396246 - VSD Patient Information (Slim Jim) - "Stop Coping Start Living."
ETH.MESH.03427757-59 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to 11.26.14)
ETH.MESH.03427878-946 - TVT IFU
ETH.MESH.03439842-46 Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"
ETH.MESH.03440816-36 - Prosima Revised Webinar Deck - Overview
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03459088-104 - Patient Brochure
ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007
ETH.MESH.03466382-83 - Email string dated 5/12/2011, top one from Kevin Frost to Benjamin Bouterie re: Dr. Bedestani; cc: Stacy Hoffman
ETH.MESH.03471308 - Chart entitled "Pedm Monthly Status."
ETH.MESH.03612364 - Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.
ETH.MESH.03626267-69 - Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.03643392-95 - Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQs and Customer Letter.
ETH.MESH.03667696 - Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Material for Medical Devices
ETH.MESH.03715978 - Weisberg email re: TVT question.

**Production Materials**

ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03736120-27 - Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03751819 - 2009 The Science of What's Left Behind
ETH.MESH.03895925-26 - Email from Frost to Affeld, et al. re: Sales Rep Training on Prosima 5/18
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905968-75 - Patient Brochure
ETH.MESH.03905968-975 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905992-6000 - Patient Brochure
ETH.MESH.03906001-020 - Prolift +M Patient Brochure
ETH.MESH.03906001-20 - Patient Brochure: What You Should Know About Pelvic Organ Prolapse. Stop Coping. Start Living. Dated 11/9/2009
ETH.MESH.03906001-20 - Prosima Brochure
ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living
ETH.MESH.03906037-52 - Patient Brochure
ETH.MESH.03907468-9 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03916905-13
ETH.MESH.03917375-378 - (11.26.2002) Email string, top one from Martin Weisberg to Dr. Richard Juraschek, et al. re: Mini TVT - mesh adjustment.
ETH.MESH.03921355-156 - Miller, D. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results.
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912-14 - The History of TVT
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results
ETH.MESH.03962244 - Dear Surgeon letter 7/18/11
ETH.MESH.03984409-10 - Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.
ETH.MESH.03989722-23 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.

**Production Materials**

ETH.MESH.03989781-82 - Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.
ETH.MESH.03991591-92 - Memo re: Gynecare Studies; created by Randall Gore.
ETH.MESH.04005090-91 - Ethicon informs FDA of discontinuation
ETH.MESH.04005092-93 - Ethicon's Notification to FDA to Decommercialize
ETH.MESH.04005095-96 - Ethicon's Notification to FDA regarding Decommercialization
ETH.MESH.04042511-12 - Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04077172 - Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re : 10100080654 and TVT IFUs
ETH.MESH.04181761-762 - Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile
ETH.MESH.04201880 - Prosima Training Deck 2
ETH.MESH.04206959
ETH.MESH.04381806-19 - Literature Review on Biocompatibility of Prolene Sutures and Impants
ETH.MESH.04427456-57 - FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems
ETH.MESH.04474731 - Ethicon's Cover Letter Response to TVT Secur 522 Order
ETH.MESH.04474733 - Ethicon's TVT Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TVT Securm System
ETH.MESH.04476265-72 - April 24 2012 email to FDA
ETH.MESH.04476274-75 - Email re: Meeting Minutes from April 18 2012 meeting w FDA
ETH.MESH.04543334 - Email re: Faculty & Customer Call Post-FDA Panel Mtg on 9/12
ETH.MESH.04543335 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04543335 - Powerpoint "Pelvic Organ Prolapse Surgical Mesh Discussion"
ETH.MESH.04543336 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04548931-35
ETH.MESH.04548975 - Email re: Piet's response to 522 FDA refusal clean
ETH.MESH.04550996-97 - Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.
ETH.MESH.04551757-795 - E-mail with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM
ETH.MESH.04551946 - Ethicon Gynecare WW Commercialization Decision – US Surgeon Letter 6/1/12
ETH.MESH.04554662 - Ethicon Gynecare WW Commercialization Decision – US Frequently Asked Questions 6/1/12
ETH.MESH.04554687 - FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29)
ETH.MESH.04556236 - Email re: Piet's takeaways from 2011 FDA meeting
ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303
ETH.MESH.04567040-44 - FDA's Response to proposed study plan-04.02.2012
ETH.MESH.04567080 - FDA's Resposne to Discontinuation and Agreement to Hold 522 Responses
ETH.MESH.04567174 - Ethicon Gynecare US Commercialization Decision – US Discussion Guide for Use with Customers 5/15/12
ETH.MESH.04567674 - Ethicon Gynecare US Commercialization Decision – Core Messages 5/15/12
ETH.MESH.04567677-79 - Frequently asked questions 5/15/12

**Production Materials**

ETH.MESH.04567680-81 - Message from Laura Angelini to Internal WW Associates 5/15/12
ETH.MESH.04567686-79 - US Sales Call Script for Matt Henderson 5/15/12
ETH.MESH.04567695 - Ethicon Gynecare WW Commercialization Decision – Core Messages 6/1/12
ETH.MESH.04567698 - Ethicon Gynecare WW Commercialization Decision – Standby Statement 6/1/12
ETH.MESH.04567707 - Ethicon Gynecare WW Commercialization Decision – Chuck Austin Message to WW General Surgery Employees 6/1/12
ETH.MESH.04567726 - Ethicon Gynecare WW Commercialization Decision – Tim Schmid message to US General Surgery Employees 6/1/12
ETH.MESH.04568448 - Email re: Piet following 2011 Ad Com
ETH.MESH.04568519 - Email dated 6/8/2012 from Matt Henderson to Tim Schmid re: 522 Communication Recap
ETH.MESH.04568717-18 - Email from Tim Schmid to Chuck Austin dated 6/8/12 re: Prolift +M withdrawal notice
ETH.MESH.04925553-91 - Postmarket Surveillance Study PS120044, Gynecare Prosima™ Pelvic Floor Systems - K063562 dated 2/1/2012
ETH.MESH.04926191-92
ETH.MESH.04927339-40 - FDA's Resposne to Discontinuation Notification-07.09.2012
ETH.MESH.04931596 - Kanerviko email re 40000 page response to 522
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevio
ETH.MESH.04939001 - Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05009194
ETH.MESH.05092843 - Chart listing lab schedule for August 11th.
ETH.MESH.05106233-34 - Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder: Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.
ETH.MESH.05164225-26 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesg and a vaginal support device."
ETH.MESH.05165675-77 - EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.
ETH.MESH.05217098-100 - FDA Clearance Letter, Modified PROLENE
ETH.MESH.05217103-44 - Letter to FDA re: Notification of Intent
ETH.MESH.05222673-705 - TVT IFU
ETH.MESH.05225354-85 - TVT IFU
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05343480-82 - Email string, top one from Joseph Lanza to Bart Pattysen re: Review EWHU IUGA events.
ETH.MESH.05343757-58 - Email string, top one from Kevin Frost to Bart Pattysen re: July 31 Heads Up; cc: Lissette Caro-Rosado.
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05469908-12 - Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery

**Production Materials**

ETH.MESH.05479535
ETH.MESH.05571741 - Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.
ETH.MESH.05573916-17 - Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.
ETH.MESH.05588123-126 - Stephen Wohler Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05741094 - Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.
ETH.MESH.05741890-91 - Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.
ETH.MESH.05795421-508 - 2001 slides from Parisi binder
ETH.MESH.05795537-99 - 1998 TVT Slide Deck
ETH.MESH.05799233-239 - TVT Exact IFU
ETH.MESH.05799233-316 - TVT-E IFU
ETH.MESH.05820723 - Dear Surgeon Letter re Discontinuation
ETH.MESH.05835298-308 - Pelvic Organ Prolapse - Patient Counseling Guide.
ETH.MESH.05837063-110 - Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.
ETH.MESH.05840629 - Powerpoint Presentation entitled "Continuum of Education."
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05922038 - Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.
ETH.MESH.05947160-63 - Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up_Gynecare_Reminder; cc: Fernando Nassif, et al.
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05967586-87 - Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.
ETH.MESH.05987605-06 - Email re: Piet's response to 522 FDA refusal
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06049894-96 - FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11
ETH.MESH.06087471-72 - TVT Patient Brochure
ETH.MESH.06087513-14 - Patient Brochure
ETH.MESH.06113091-92 - Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.
ETH.MESH.06124656-57 - Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.
ETH.MESH.06124954-55 - Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.
ETH.MESH.06125000-01 - Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.
ETH.MESH.06125058 - Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.
ETH.MESH.06125098 - Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.

**Production Materials**

ETH.MESH.06125277 - Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.
ETH.MESH.06125309 - Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.
ETH.MESH.06125502 - Email string, top one from Georgia Long to Bart Pattyson re: may 8th.
ETH.MESH.06151466-67 - Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.
ETH.MESH.06238611 - Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.
ETH.MESH.06255523-34 - Gynecare Prosima Pelvic Floor Repair System: An expert interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the inventor of the Gynecare Prosima system
ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361
ETH.MESH.06388151 - Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints
ETH.MESH.06480608-09 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.06482821-22 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.
ETH.MESH.06585815 - Powerpoint: Agenda
ETH.MESH.06591558-59 - Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06769156 - Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.07105727 - Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.
ETH.MESH.07189091 - Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.
ETH.MESH.07190144-45 - Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)
ETH.MESH.07219196-209 - Clinical Expert Report - Prosima <sup>™</sup> signed by David Robinson.
ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07229215-45 - Clinical Expert Report - Prosima <sup>™</sup> signed by Piet Hinoul.
ETH.MESH.07229312-42 - Clinical Expert Report Gynecare Prosima <sup>™</sup> Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012

**Production Materials**

ETH.MESH.07246690-719 - Study Report dated May 8, 2012: A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.07296496 - Chart listing Week Schedule and Lab Flow.
ETH.MESH.07308636-37 - Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.
ETH.MESH.07324554-555
ETH.MESH.07351297 - Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>
ETH.MESH.07374762-63 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.07379573-74 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07384790-91 - Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.07587090-91 - Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.
ETH.MESH.07628243 - EWH&U Gynecare Prosima™ Pelvic Floor Repair System Faculty Checklist.
ETH.MESH.07630654 - Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.
ETH.MESH.07631488 - Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.
ETH.MESH.07631752-53 - Email string, top one from Eric Globberman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.
ETH.MESH.07631967-68 - Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.
ETH.MESH.07632042 - Event request form for Sepulveda Preceptorship.
ETH.MESH.07632042-43 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.07636090 - Prosima Cadaver Lab Invitation
ETH.MESH.07653362-63 - Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.07931680-81 - Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.07951163 - Document re: Prosima's apical/anatomical success rates and functional outcomes.
ETH.MESH.07953429-33 - EWH&U 2011 Field Visit Letter
ETH.MESH.07977911
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003247-62 - Patient Brochure
ETH.MESH.08003263-78 - Patient Brochure
ETH.MESH.08003279-94 - TVT Patient Brochure
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08021804-07 - Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.

**Production Materials**

ETH.MESH.08023741-44 - Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.
ETH.MESH.08033153 - Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Lubner, Charles W. Nager, Emily S. Lukacz.
ETH.MESH.08048738-40 - Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.
ETH.MESH.08066452
ETH.MESH.08107354 - Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides
ETH.MESH.08117473 - 2012 TVT-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08117625-26 - Prolift +M Profession Education Slide Deck
ETH.MESH.08135444 - Gynecare Prosima - Pelvic Floor Repair System Proctorship
ETH.MESH.08139049-118 - Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.
ETH.MESH.08156958 - 2002 TVT Advanced Users Forum Presentation
ETH.MESH.08161765 - Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.
ETH.MESH.08169582-620 - Surgical Practice of POP survey on Survey Monkey.
ETH.MESH.08290691
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08309057-92 - Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."
ETH.MESH.08315779-810 - Clinical Expert Report Gynecare Prolift +M™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08375158-59 - Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TVT Abbrevio, Prosima, TVT Exact.
ETH.MESH.08384247
ETH.MESH.08384270 - Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garriss.
ETH.MESH.08421628 - Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12
ETH.MESH.08476311 - Cytotoxicity assessment of Ulstem sling
ETH.MESH.08492824 - Strategic Business Team Meeting - Meeting Notes
ETH.MESH.08565137-41
ETH.MESH.08640676 - Jones email 4/04/08 re Prosima update for RBDs
ETH.MESH.08791917
ETH.MESH.08945734-35 - ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."
ETH.MESH.08945742-44 - Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.
ETH.MESH.08945836-40 - Document entitled "Gynecare Prosima Claims List."
ETH.MESH.08948364-65 - Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.

**Production Materials**

ETH.MESH.08951725-26 - Email string, top one from Tom Affeld to Kevin Frostr re: Prosima 2 year summary for eClinical Compendium.
ETH.MESH.08961175-76
ETH.MESH.08962682-83 - Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.
ETH.MESH.08962684-85 - Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.
ETH.MESH.08971152-53 - Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.
ETH.MESH.08971269-70 - Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.
ETH.MESH.08971271-72 - Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.
ETH.MESH.08971309-14 - Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.
ETH.MESH.08988155 - Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.
ETH.MESH.08988298-417 - EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.
ETH.MESH.09050450 - Memorandum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).
ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)
ETH.MESH.09128451 - Chart entitled "Faculty Training."
ETH.MESH.09128545 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11
ETH.MESH.09138054-55 - Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinis, M.D.
ETH.MESH.09142383-84 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.09142511 - (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.
ETH.MESH.09144349 - Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.
ETH.MESH.09191424-26 - Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.
ETH.MESH.09207059 - Chart entitled "Grier."
ETH.MESH.09218452-53 - Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09283030 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283031 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283032 - Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283033 - Spreadsheet re: Budget Summary
ETH.MESH.09283034 - Spreadsheet re: Integrated Marketing
ETH.MESH.09283035 - Spreadsheet re: Summary
ETH.MESH.09283036 - Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283037 - Spreadsheet re: Budget Summary
ETH.MESH.09283038 - Spreadsheet re: Integrated Marketing

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ETH.MESH.09290755 - Spreadsheet re: Q1 2012 Open PO Summary
ETH.MESH.09290760 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09290767 - Spreadsheet re: Uterine Health
ETH.MESH.09290769 - Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary
ETH.MESH.09290772 - Spreadsheet re: Budget Summary
ETH.MESH.09300480 - Spreadsheet re: Prosima All Day
ETH.MESH.09625725-29 - Government Submissions Log Sheet
ETH.MESH.09625731-37 - FDA Letter. re: approved drug application for polypropylene suture.
ETH.MESH.09625816 - FDA letter re: receipt of drug application for polypropylene suture.
ETH.MESH.09625817 - Letter to FDA re: new drug application for Polypropylene Suture.
ETH.MESH.09629447-48 - FDA Labeling Approval for Prolene
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09630649 - FDA Letter re: package insert for Prolene.
ETH.MESH.09634081 - Sections 6 re: adverse effects.
ETH.MESH.09634299-303 - FDA Letter re: approval of PMA supplement.
ETH.MESH.09634318 - Prolene Package Insert.
ETH.MESH.09634662-63 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09634664-88 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744840-45 - Patient Brochure
ETH.MESH.09744848-55 - Patient Brochure
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study
ETH.MESH.09922570-578 - TVTO PA (TOPA) R&D Memorandum of PA Mesh Assessments for TVTO-PA Katrin Elbert Dec.Revision 1
ETH.MESH.10027307-28 - TVT Surgeons Resource Monograph - June 2000
ETH.MESH.10048035-36 - Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.
ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynecare Gynemesh™ PS Nonabsorbable Prolene™ Soft Mesh signed by Piet Hinoul on 04.26.2013
ETH.MESH.10220659 - Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician
ETH.MESH.10224077 - Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.
ETH.MESH.10232708 - Email from Stevan Barendse to Greg Prine re: Prosima targets.
ETH.MESH.10281860 - 2013 Clinical Expertise TVT Prof Ed Slide Deck
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.
ETH.MESH.10376963
ETH.MESH.10378001-02
ETH.MESH.10384309-310

**Production Materials**

ETH.MESH.10399553 - Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.
ETH.MESH.10608341-57 - Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.
ETH.MESH.10817931 Pelvic Mesh Post-Market Surveillance Orders April 2012
ETH.MESH.10960414 - Email from Christopher O'Hara to Francois Barbe, et al. re: VRT for Prosima.
ETH.MESH.11048537-38 - Prosima E-blast No. 1 "The Proof of Success."
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report
ETH.MESH.11448841 - Conference Participant Report 8/25/11
ETH.MESH.11518663-65 - Email string, top one from Melissa Doyle to Arthur Mourtzinis re: Agenda for tomorrow's lab.
ETH.MESH.11522550-51 - Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.
ETH.MESH.11523079 - Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.
ETH.MESH.11524125-28 - Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.
ETH.MESH.11536046 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.
ETH.MESH.11538048-49 - Email from Frost to Globerman, et al. re: prosima usage northeast
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.11905619 - Spreadsheet: Prosima Virtual Roundtable Calls &Targets
ETH.MESH.1210987-95 - Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal
ETH.MESH.1222075-79 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12897617-78 - 2013 Clinical Evaluation Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.13314554 - Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.
ETH.MESH.13532200 - Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12
ETH.MESH.13592561 - Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"
ETH.MESH.13618003-04 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.13618029-31 - EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."
ETH.MESH.13622000-70 - Prosima Trainee Deck Distribution
ETH.MESH.13635675 - 2011 B&W POP & SUI Patient Counseling Guide production copy
ETH.MESH.1363575.NATIVE
ETH.MESH.13645631 - DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.
ETH.MESH.13698543 - Prosima Marketing Material Roll-Out Letter.

**Production Materials**

ETH.MESH.13698840-59 - Bart Pattyson editorial re prof ed bulletin
ETH.MESH.13699674 - Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.
ETH.MESH.13756212-18 - Clinical study Finding Discussion for Gynecare Prosima™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).
ETH.MESH.13756219 - Gynecare Prosima™ Pelvic Floor Repair System MRI Address
ETH.MESH.13756384 - Prosima Virtual Round Table Trainee Confirmation
ETH.MESH.13756409 - Prosima Virtual Round Table Preceptor Follow-up and Invitation.
ETH.MESH.13756416-17 - Prosima Virtual Round Table Preceptor Confirmation.
ETH.MESH.13869166 - Powerpoint: Mint Project - Pelvic Floor Repair.
ETH.MESH.14427453-55 - FDA Clearance Letter re: K063562 Gynecare Prosima™
ETH.MESH.14427459-43 - Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.
ETH.MESH.14427562-63 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.14427564-65 - FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)
ETH.MESH.14427567-69 - Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.
ETH.MESH.14427578-61 - TraditionsI 510(k) Premarket Notification Gynecare Prosima™ Pelvic Floor Repair System.
ETH.MESH.15958178-82 - Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQs and Customer Letter.
ETH.MESH.161953-54 - 10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture Gynecare TVT Obturator System Sales Materials
ETH.MESH.16259973 - Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports
ETH.MESH.16350627-28 - Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.
ETH.MESH.16352932-34 - Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.
ETH.MESH.1751069-94 - 09/07/2009 Safety review: TVT and TVT-O procedures
ETH.MESH.17669942 - Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.17748760-61 - E-mail 4.25.11 from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.1784779-82 - Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) RiskAnalysis
ETH.MESH.1784823-28 - Clinical Expert Report
ETH.MESH.1809056-58 - Email re: Important Laser cut mesh update
ETH.MESH.1809080-81 - Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641)
ETH.MESH.1815660-64 - Project Mulberry, Preliminary Clinical Diligence Report
ETH.MESH.18844812 - Jan 2007 email re delaying launch
ETH.MESH.18844812- Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse.
ETH.MESH.19308264-65 - Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.
ETH.MESH.19310234-38 - Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TVT-O

**Production Materials**

ETH.MESH.222852-863 - 12/15/2003, Gynecare Final Report # 03*0740, TVT Obturator System
ETH.MESH.222899-909 - Clinical Expert Report
ETH.MESH.2236604-609 - TVT Obturator Brochure; "Results, Precision & Proven Mesh"
ETH.MESH.223779-84 - Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3
ETH.MESH.22937156 - Email from Dan Smith re: NG TVT-O NDP – Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny
ETH.MESH.2340504-33 - TVT IFU
ETH.MESH.2340902-08 - TVT O IFU
ETH.MESH.262089-123 - Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out
ETH.MESH.3364663-66 - Email from O'Bryan re: ifu
ETH.MESH.3365250-251 - Email from Weisberg re: IFU update
ETH.MESH.341006-11 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMCP15506/E) Update (Part II, RA0001-2010, Rev. 1)
ETH.MESH.3427878-83 - TVT IFU
ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TVT System
ETH.MESH.3911390-1 - Email from Arnaud re: Transient Leg Pain with Mulberry
ETH.MESH.3922926-28 - Email re: OR Agenda Tunn
ETH.MESH.3932909-11 - History of TVT-O
ETH.MESH.3934952-67 - Tension-Free Vaginal Obturator Tape (TVOT) – April 30, 2003 – Meeting Report
ETH.MESH.4048515-20 - KOL Interview
ETH.MESH.4384126-65 - Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide
ETH.MESH.442825-26 - Email re: TVT Laser Mesh info
ETH.MESH.524746-48 - Email re: TVT Meeting with Agency
ETH.MESH.525573 - Email re: TVT Laser Cut Mesh
ETH.MESH.5315252-65 - Final Report, PSE Accession No. 97-0197, Project No. 16672
ETH.MESH.658177-98 - TVT Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting
ETH.MESH.6696411-19 - Email re: Performance Evaluation of TVT Prolene Blue Mesh
ETH.MESH.6859834-35 - Email re: Laser Cut TVT
ETH.MESH.6878438-39 - Memo re: VOC on new Laser Cut TVT Mesh
ETH.MESH.6882641-642 - Email from O'Bryan re: GYNECARE TVT Obturator System – FDA
ETH.MESH.6886410-11 - Email from Weisberg re: Mulberry
ETH.MESH.7393700 - 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician Training Policy
ETH.MESH.7692905-07 - Email re: Mesh Fraying Dr. EBERHARD letter
ETH.MESH.8003295-301 - Patient Brochure: "Stop coping, start living."
ETH.MESH.8003303-17 - Patient Brochure: "Stop coping, start living."
ETH.MESH.823793-806 - Transobturator Vaginal Tape Inside-Out (TVT-O): From Development to Clinical Experience
ETH.MESH.865069-72 - Email from Dan Smith re: Draft report translated by "Babel fish" <a href="http://babelfish.altavista.com/tr">http://babelfish.altavista.com/tr</a>
ETH.MESH.PM.000001 - Prolift Professional Education Videos
ETH.MESH.PM.000002 - TVT-O Procedural Video

**Production Materials**

ETH.MESH.PM.000006 - Anatomy Videos
ETH.MESH.PM.000007 - Prolift Professional Education Videos
ETH.MESH.PM.000009 - Anatomy Videos
ETH.MESH.PM.000014 - Prolift Professional Education Videos
ETH.MESH.PM.000015 - Prolift Professional Education Videos
ETH.MESH.PM.000019 - Prolift Professional Education Videos
ETH.MESH.PM.000027 - Prolift Professional Education Videos
ETH.MESH.PM.000032 - Prolift Professional Education Videos
ETH.MESH.PM.000033 - Prolift Professional Education Videos
ETH.MESH.PM.000034 - Prolift +M Professional Education Videos
ETH.MESH.PM.000037 - Prolift Professional Education Videos
ETH.MESH.PM.000038 - Prolift Professional Education Videos
ETH.MESH.PM.000039 - Prolift Professional Education Videos
ETH.MESH.PM.000042
ETH.MESH.PM.000045
ETH.MESH.PM.000048 - Prolift +M Professional Education Videos
ETH.MESH.PM.000057 - Anatomy Videos
ETH.MESH.PM.000058 - Prolift Professional Education Videos
ETH.MESH.PM.000059
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068 - Anatomy Videos
ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
ETH.MESH.PM.000083
ETH.MESH.PM.000084
ETH.MESH.PM.000087
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000089 - Anatomy Videos
ETH.MESH.PM.000090 - Anatomy Videos
ETH.MESH.PM.000092 - Prolift +M Professional Education Videos
ETH.MESH.PM.000093
ETH.MESH.PM.000094
ETH.MESH.PM.000095
ETH.MESH.PM.000096
ETH.MESH.PM.000097
ETH.MESH.PM.000098
ETH.MESH.PM.000130
ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000143
ETH.MESH.PM.000145 - Prolift +M Professional Education Videos
ETH.MESH.PM.000148
ETH.MESH.PM.000151 - Anatomy Videos
ETH.MESH.PM.000154 - Anatomy Videos
ETH.MESH.PM.000156
ETH.MESH.PM.000157
ETH.MESH.PM.000170

**Production Materials**

ETH.MESH.PM.000171
ETH.MESH.PM.000179 - TVT Secur IFU V5e 2005 to disc (Original from Prof Ed DVD)
ETH.MESH.PM.000179 - TVT-Secur Key Tech Points 5.24.2007 (Color Original from Prof Ed DVD)
ETH.MESH.PM.000190 - Prolift Professional Education Videos
ETH.MESH.PM.000192 - Prolift Professional Education Videos
ETH.MESH.PM.000202
ETH.MESH.PM.000246
ETH.MESH.PM.000257
ETH.MESH.PM.000272
ETH.MESH.PM.000273
ETH.MESH.PM.000274
ETH.MESH.PM.000288
ETH.MESH.PM.000303
ETH.MESH.PM.000306
ETH.MESH.PM.000309
ETH.MESH.PM.000316
ETH.MESH.PM.000317
ETH.MESH.PM.000318
ETH.MESH.PM.000319
ETH.MESH.PM.000320
ETH.MESH.PM.000321
ETH.MESH.PM.000322
ETH.MESH.PM.000336
ETH-00254-261 - Patient Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2006
ETH-00295-300 - Exh. 10 Gynecare Prolift IFU dated 2004
ETH-00797-829 - 510(k) Notification Gynemesh Prolene™ Soft Nonabsorbable Synthetic Surgical Mesh.
ETH-00807-808 - FDA Clearance letter for Gynemesh soft mesh for pelvic floor repair
ETH-00830-861 - Labeling/Package Insert
ETH-00862-893 - Test Method for the Determination of Mesh Burst Strength for Prolene Soft Mesh.
ETH-00894-927 - Medical Literature
ETH-01363-365 - Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512
ETH-01816-817 - FDA Clearance Letter, Prolene Soft Mesh (K001122)
ETH-02386 - Cosson, M. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results
ETH-02387 - Lucente, V. Prospective clinical assessment of the total vaginal mesh (TVM) Technique for treatment of pelvic organ prolapse - 6 and 12 month results.
ETH-02388 - Amblard, J. From the TVM to the Prolift® (Gynecare): evolution of a technique for prosthetic support to treat prolapse via the vaginal route, concerning a retrospective multicentric series of 794 patients (684 TVM/110 Prolift)
ETH-02653 - Fatton, B. Preliminary results of the "Prolift™" Technique in the treatment of pelvic organ prolapse by vaginal approach: a multicentric retrospective series of 110 patients. IUGA 2006 Athens Non-discussed Abstract 275

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ETH-02750-755 - Hinoul P. A Prospective Study to Evaluate the Anatomic and Functional Outcome of a Transobturator Mesh Kit (Prolift Anterior) for Symptomatic Cystocele Repair. Journal of Minimally Invasive Gynecology (2008) 15, 615-620
ETH-03220-221 - Cosson, M. Preservation of uterus when treating prolapse by Prolift TM does not significantly reduce risk of early post-surgical complications and failures. ABS 89
ETH-03223 - Dedet, B. Transvaginal repair of genital prolapse by the Prolift technique: outcome one year after surgery.
ETH-03227-228 - Dati, S. Prolift vs. Avaulta for transvaginal repair of severe pelvic prolapse
ETH-03568-578 - (03.01.2005) Summary Memo for Revision B of the Gynecare Prolift Design Failure Modes Effects Analysis (dFMEA).
ETH-07153-158 - Gynecare Prolift Clinical Expert Report signed by Charlotte Owens on 01.14.05.
ETH-07247-303 - (03.02.2005) Approvals and Summary Memo for Version A of the Gynecare Prolift Application Failure Modes Effects Analysis (aFMEA).
ETH-07252-281 - Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique
ETH-10505-596 - 2008 Prolift Slide deck
ETH-10977-983 - Gynecare Prolift IFU dated 2009
ETH-18415 - Memo to Hospital Materials Managers & or Directors from Gynecare Worldwide Ethicon dated 10.10.02 regarding Gynecare Gynemesh*PS
ETH-37788-793 - Gynecare Prolift Clinical Expert report
ETH-60188-195 - Hiltunen R. Low-Weight Polypropylene Mesh for Anterior Vaginal Wall Prolapse - A Randomized Controlled Trial. Obstet Gynecol 2007;110-455-62
Ethicon Final Report, PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035)
Ethicon Technical Report: Assessment of Competitor Pelvic Floor Repair Meshes, Version 1; Study Number: CPC-2006-0552; JJ-HMREV-00016715
Ethicon Women's Health & Urology — Clinical Compendium — Sales Rep Positioning [ETH.MESH.0011879; ETH.MESH.00093830]
EWHU Faculty and PF User Conference Calls Outline
Exh. 59 – Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile (2 pages)
Guidance for Industry and FDA Staff. "Class II Special Controls Guidance Document: Surgical sutures; Guidance for Industry and FDA."
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience dated in 2003 (8 pgs)
Gynecare Gynemesh PS IFU (English Only) LAB-0012266 Rev: 3, released 02.03.15.
Gynecare Prolift - Product Devise Design Safety Assessment (DDSA)
Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique (30 pgs)
Gynecare Prosima - Content for Ethicon360.com
Gynecare Prosima (K063562) Summary of Safety and Effectiveness
Gynecare Prosima updates to ethicon360.com
Gynemesh PS Approval File (FDA) Requested August 15, 2007 Folder: K013718 - 131 pages; Summary: Product: GYNEMESH PROLENE SOFT (POLYPROPYLENE) NON ABSORBABLE SYNTHETIC SURGICAL
Gynemesh PS Approval File from FDA website (K013718)

**Production Materials**

HMESH.ETH.11642462 – Franchise Regulatory Labeling Guidance
JJM.Mesh.00043703 Response Statement and FAQs – FDA Notification about use of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter from FDA re: Postmarket Surveillance (PS) Study: PS120044 (Prosima 522 Order)
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Letters to and from the FDA re: Prolene, Polypropylene Nonabsorbable Surgical Suture, USP.
Librojo updated TVT Declaration (10-23-15) [12 pages]
McCabe email re - Sheath Sales Tool - 464
Memo to S. Ciarrocca re: Regulatory Strategy - Project D'Art; Rev 3
Mesh Information for Patients with Pelvic Floor Disorders
MSDS-Marlex Polypropylenes
Notice of Claimed Investigational Exemption for a New Drug (1-125)
Notice of Claimed Investigational Exemption for a New Drug (126-253)
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
Pelvic Organ Prolapse Patient Counseling Guide
Powerpoint - GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
Powerpoint - Prospective Clinical Assessment of TVM - 1 Year Results
Powerpoint Presentation entitled "Trocars & Pelvic Anatomy: Do They Mix Well?"
Presentation: Non Absorbable Sutures
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Seven Year Dog Study - T-2263
Slide Presentatopm "Gynecare Prosima ™ Pelvic Floor Repair System
Summary of Safety and Effectiveness submitted by Bryan Lisa for Gynecare Prolift and Prolift +M stamped 5.15.08 (2 pgs)
Supplement Numbers and Application Dates
Surgeon's Rescource Monograph for TVT
TVM Prospective 6 month Data
TVT Abbrevio IFU - 01.2015
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TVT-Obturator IFU - 01.2015
TVT-R Prof Education Slide Deck
Video titled Prosima Shortened Procedure. Hydrodissection and Dissection.
Video: 2010 Prosima Testimonial for NTM
Wound Closure Manual

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<b>Deponent [Date of Deposition]</b>
Angelini, Laura [09.16.2013]
Angelini, Laura [09.17.2013]
Angelini, Laura [11.14.2013]
Arnaud, Axel [11.15.12]
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Austin, Charles E. - 08.13.2015
Barbolt, Thomas [1.7.2014]
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Barbolt, Thomas Ph.D. [10.10.12]
Barbolt, Thomas Ph.D. [10.9.12]
Batke, Boris [8.1.2013]
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Beach, Patricia [6.17.13]
Beath, Catherine [11.8.12]
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Brown, Allison [9.11.13]
Burkley, Dan F [5.22.2013]
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Chahal, Ricky [12.10.2014]
Chen, Meng [10.29.2013]
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Chen, Meng [10.30.2013]
Chen, Meng [10.4.2012]
Courts, Paul [6.11.15]
Elbert, Katrin [12.23.14]
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Gauld, Judith [11.8.13] [4.27.12]
Grier, Douglas [12.30.2014]
Hart, James [12.20.13]
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Hinoul, Piet [01.13.2014]
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Hinoul, Piet [6.27.2013]
Hinoul, Piet M.D., Ph.D. [4.5.12]
Hinoul, Piet M.D., Ph.D. [4.6.12]
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Hinoul, Piet M.D., Ph.D. [9.19.12]
Holste, Joerg [12.14.12]
Holste, Joerg [12.15.12]
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Horton, Ronald, M. - 07.01.2015
Isenberg, Richard [11.05.2013]
Isenberg, Richard [11.06.2013]
Jones, Gregory R [8.20.2013]
Kammerer, Gene [01.17.2014]
Kammerer, Gene [01.28.2014]
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Kammerer, Gene [10.17.12]
Kammerer, Gene [12.03.2013]
Kammerer, Gene [12.05.2013]
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Kanerviko, Brian [8.23.13] [8.22.13]
Kirkemo, Aaron [01.06.2014]
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Lamont, Dan [4.3.2013]
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Lin, Susan [3.12.2013]
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Lisa, Bryan [12.19.11]
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Lisa, Bryan A [4.25.2013]
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Luscombe, Brian [7.29.13]

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Meek, Jonathan [2.24.12] [9.11.12]
Nager, Charles - 06.10.2014 Deposition Testimony
Owens, Charlotte [6.19.2013]
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Parisi, Paul [6.6.13]
Peebles, Rhonda [07.16.2014]
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Robinson, David [7.24.2013]
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Schmid, Tim - 07.31.2015
Selman, Renee Elayne [6.20.2013]
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St Hilaire, Price [7.11.13]
Vailhe, Christophe [6.20.13]
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Volpe, Clifford [2.28.12] [2.29.12]
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Oxford Levels of Evidence; <a href="http://www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg">www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg</a>
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<b>Other</b>
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02.01.2012 Prosima Postmarket Surveillance Study PS120044; Gynecare Prosima Pelvic Floor Repair Systems
2009 AUA Prosima Slide - A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. (Zyczynski, H.)
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2011 Khandwala ICS Poster - Prosima
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Gynecare Prosima content for ethicon360.com [5 pages]
Gynecare Prosima Procedural Steps DVD
Gynecare Prosima updates to ethicon360.com PROS-314-11-8/12 [113 pages]
Gynecare Prosima VSD Patient Brochure 2009: Stop Coping, Start Living. [2 pages]
Gynecare Prosima VSD Patient Information Slim-Jim: What you should know about the Gynecare Prosima Vaginal Support Device; Stop Coping. Start living™ [2 pages]
Gynecare Prosima™ AIDiNC Selling Guide- Your Guide to Selling Gynecare Prosima™ with the AIDiNC process [16 pages]
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Proxima 2011 Sales Aid- What Could a Truly Tension-Free Repair Mean for you and your Patients? [20 pages]
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Prosima cadaver lab invitation- Gynecare Proxima™ Pelvic Floor Repair System Cadaver Lab [1 page]
Prosima Combined Exemplar (PROC2)
Prosima E-Blast No. 1- The Proof of Success [2 pages]
Prosima Launch Sales Aid- Your Proof: Her dance class [3 pages]
Prosima Marketing Material Roll-out Letter from Kevin Forst PROS-040-10-2/12 February 16, 2010 [1 page]
Prosima MRI Flashcard 2- Gynecare Proxima™ Pelvic Floor Repair System. The first fixationless mesh system that maintains anatomical position. [2 pages]
Prosima MRI Flashcard- MRI Flashcard Learning Guide [2 pages]
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Prosima Revised Webinar Deck- [21 pages]
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Prosima Testimonial for NTM 2010 Video
Prosima Touch Workshop Key Takeaway [2 pages]
Prosima Trainee Confirmation- Virtual Round Table October 2010 [1 page]
Prosima Trainee Invite- Advanced Pelvic Floor Course with Gynecare Proxima Saturday, October 24, 2009 [1 page]
Reisenauer Summary Positioning Proxima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [2 pages]
Testimonial Videos
TVT & TVT-O Long Term Studies (94 pages)
TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months (Plaintiff's Exhibit 2272)
Zycynski Summary Positioning Proxima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary

**Mary Shelton - Case Specific**

<b>Depositions</b>
Shelton, Frank - 03.24.2016
Shelton, Mary - 03.24.2016
Unger, James B. - 05.27.2016
<b>Expert Reports</b>
Galloway, Niall (Case Specific) - 05.05.2016
Iakovlev, Vladimir (Case Specific) - 04.29.2016
Guelcher, Scott (General) - Received 05.05.2016
Iakovlev, Vladimir (General) - 01.29.2016
Ostergard, Donald (Prolift, Gynemesh, Prolene General) - 01.31.2016
Wilson, Anne (General TVT) - Received 05.05.2016
<b>Other</b>
Implants - Sticker and Identifying Information
Operative Report Implants
Clinical Imagery Excision
Operative Report Excision
Pathology Report Excision
<b>Medical Records</b>
Annisian, Laura E., MD - Medical 1-20
Annisian, Laura E., MD - Medical 21-21
Aston Urology Clinic - Medical 1-151
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Barksdale Base Pharmacy - Billing 1-3
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Brookshire Pharmacy Headquarters - Billing 1-9
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Centers for Medicare and Medicaid Services - Insurance 1-1
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Champus Tricare-South Region Claims - Insurance 1-50
Christus Health Shreveport-Bossier - Radiology 1-1
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Mailhandlers First Health - Insurance 1-2
Medicaid State of Louisiana - Insurance 1-2
OBGYN Associates of Shreveport - Medical 1-1
Omega Diagnostics, LLC - Medical 1-85
Pizarro, Antonio, MD - Medical 1-70
Plaintiff Fact Sheet 1-27
Plaintiff Profile Form 12-17
Plaintiff Profile Form 1-5
Plaintiff Profile Form 6-11
Plaintiff Supplied Records 1055-1598
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Plaintiff Supplied Records 1599-2142
Plaintiff Supplied Records 2143-2146
Plaintiff Supplied Records 2147-2148
Plaintiff Supplied Records 511-1054
Primary Care Associates - Medical 1-268
Primary Care Associates - Medical 269-422
Quest Diagnostics Incorporated - Medical 1-1
Quest Diagnostics Incorporated - Medical 2-5
Quest Diagnostics Incorporated - Pathology 1-3
Quest Diagnostics Southwest - Billing 1-2
Regional Urology, LLC - Medical 1-1
Regional Urology, LLC - Medical 2-2
Rembert, Paula E., MD - Medical 1-29
Rembert, Paula E., MD - Medical 30-41

**Mary Shelton - Case Specific**

St. Michael's Hospital - Billing 1-1
St. Michael's Hospital - Medical 1-1
Supplemental medical, pharmacy, and employment records for Mary Shelton
TriCare for Life Third Party Liability Dept - Insurance 1-14
Tri-State Medical Center - Medical 1-15
University Health - Medical 1-1
University of Texas Southwestern Medical Center - Billing 1-3
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Wright Patterson Medical Center - Pathology 1-1
Wright Patterson Medical Center - Pathology 2-2
Wright Patterson Medical Center - Radiology 1-1
Wright Patterson Medical Center - Radiology 2-3

**MDL Wave Cases**

<b>Depositions</b>
Blaivas, Jerry, M.D. (General Plaintiff Expert-Prolift) - 03.02.2016
Blaivas, Jerry, M.D. (General Plaintiff Expert-TVT-S & Abbrevio) - 03.03.2016
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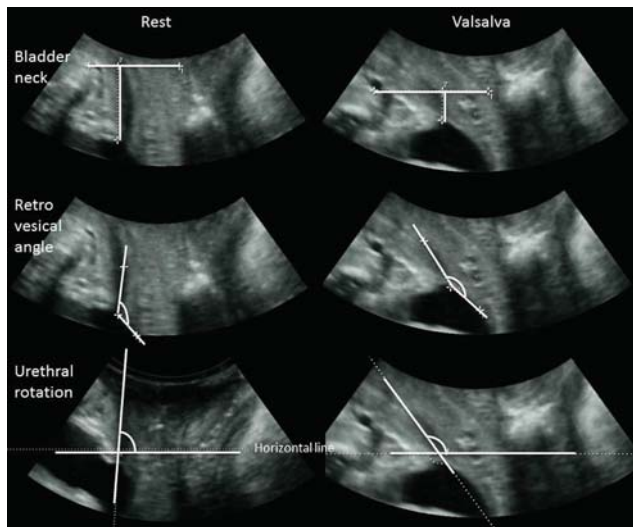


Table 1

	Variable	Group	Antenatal N=180	1 year pp N=147	4 years pp N=147	Significant differences over time
UI symptoms	ICIQ-SF score (range 0–24) Mean (SD)	≥1 CS	3.7 (4.8)	2.9 (4.5)	3.8 (5.2)	Antenatal to 1y (p=0.27)
		≥1 VD LAM intact	3.0 (3.8)	2.7 (3.4)	3.7 (4.2)	Antenatal to 4 y (p=0.34)
		≥1 VD LAM avulsion	3.1 (3.5)	3.1 (3.2)	3.2 (3.9)	1y to 4y (p=0.04)
Bladder neck and urethral mobility	Bladder neck descent (cm) Mean (SD)	≥1 CS	1.0 (0.9)	1.0 (0.8)	1.2 (0.6)	Antenatal to 1y (p=0.22)
		≥1 VD LAM intact	0.9 (0.7)	1.1 (0.8)	1.3 (1.2)	Antenatal to 4y (p<0.01)
		≥1 VD LAM avulsion	1.0 (0.7)	1.1 (0.6)	1.8 (0.8)	1 y to 4y (p<0.01)
	Urethral rotation (degrees) Mean (SD)	≥1 CS	25 (23)	33 (23)	40 (21)	Antenatal to 1y (p<0.01)
	Retro vesical angle at Valsalva (degrees) Mean (SD)	≥1 VD LAM intact	23 (17)	38 (22)	42 (24)	Antenatal to 4 y (p<0.01)
		≥1 VD LAM avulsion	26 (18)	46 (21)	47 (25)	1 y to 4y (p=0.046)
		≥1 CS	149 (25)	139 (30)	152(31)	Antenatal to 1y (p=0.32)
		≥1 VD LAM intact	146 (23)	148 (28)	160 (27)	Antenatal to 4y (p=0.02)
		≥1 VD LAM avulsion	148(19)	146 (37)	155 (30)	1 y to 4y (p<0.01)

PP 19

## THE MYTH: IN VIVO DEGRADATION OF POLYPROPYLENE MESHES

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### Abstract:

**Introduction:** Use of polypropylene (PP) hernia and urogynecological meshes began in the 1960s. Some have recently observed cracked surfaces on explanted meshes and

proposed those as degraded PP, without considering the formalin fixation process and inadequate mesh cleaning.

**Objective:** Analyze morphology and material chemistry of explanted Prolene meshes via a novel, effective, cleaning process.

**Methods:** Explanted Prolene meshes were cleaned using distilled water (to reverse the well-known chemistry of the fixative crosslinking reaction), sodium hypochlorite and Proteinase K. At each intermediate cleaning step, analysis included Light Microscopy, Fourier Transform Infrared Spectroscopy, and Scanning Electron Microscopy.

**Results:** Identical translucent and sometimes clear cracked/flaking material on blue and clear fibers was observed (Fig. 1).



Fig. 1: Had Prolene been oxidized, *in vivo* blue fiber flakes would be blue and clear fiber flakes would be clear, instead of identical translucent/sometimes clear cracked and flaking material and both blue and clear fibers.

Had Prolene been oxidized, blue fiber flakes would be blue and clear fiber flakes would be clear. Cleaning progressively removed bulk tissue and regions with cracked material on the explant surfaces, exposing clean, smooth, unoxidized and non-degraded fibers with no visible gradient-type, ductile damage, which would have occurred if Prolene degraded *in vivo* (Fig. 2).

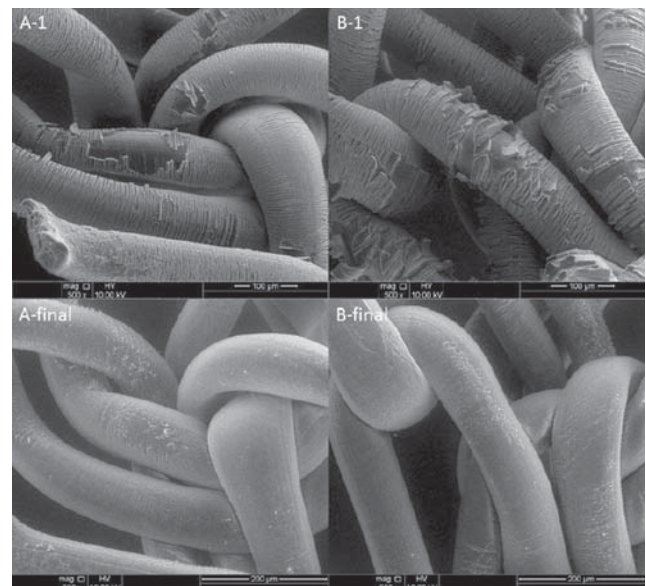


Fig. 2: SEM images showing progressive removal of cracked material at two locations (A and B) on explanted Prolene mesh after bulk tissue removal (A-1, B-1) and after progressive cleaning (A-final, B-final).

EDS showed magnesium, phosphorus, and calcium, etc. in cracked regions, but not in non-cracked regions or exemplar fibers. These are elements common to biological matter. FTIR of explants spectrally absorbed at  $\sim 1740$   $\text{cm}^{-1}$ , which others have stated as consistent with oxidative degradation. However, this absorption represents a Prolene antioxidant. An absorption frequency of  $1650$   $\text{cm}^{-1}$  is attributed to byproducts of oxidative degradation, but is within protein's absorption region and expected to be present. FTIR confirmed progressive protein removal and loss of protein absorption intensity after each cleaning step (Fig. 3).

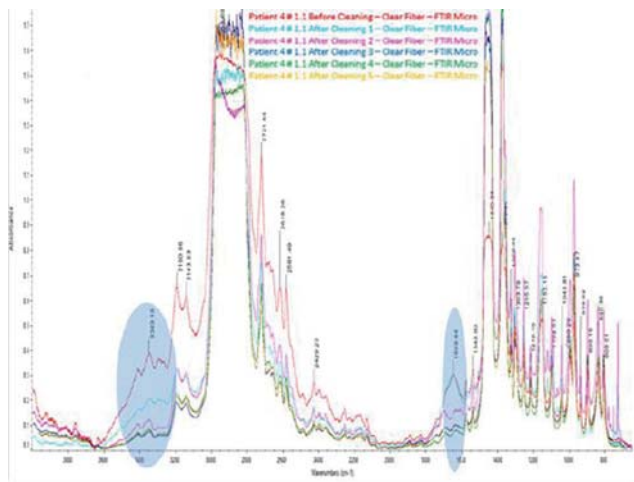


Fig. 3: FTIR showing progressive loss of adsorbed protein coating with cleaning.

**Conclusions:** Explanted Prolene meshes did not undergo meaningful or harmful degradation in vivo. Instead, the cracked layer was composed of adsorbed protein coating arising from a well-established phenomenon occurring immediately upon implantation in vivo. Adsorbed proteins when placed in formalin fixative begin immediately to crosslink and forms a hard, brittle, protective composite layer.

**References:** n/a

PP 20

# MOLECULAR EFFECTS OF INTRAVENOUS MUSCLE-DERIVED STEM CELLS THERAPY IN THE DAMAGED URETHRAL TISSUE OF FEMALE RATS: GENE AND PROTEIN EXPRESSION PROFILE.

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## Abstract:

**Introduction:** Stress urinary incontinence (SUI) is a high prevalent condition in women.

Cell therapy has been considered as a promising therapy for SUI. Since muscle-derived stem cells (MDSC) can be obtained easily in large quantities, these cells may exhibit advantages in cell therapy applications in patients with SUI.

**Objective:** Our aims were to analyze the effects of MDSC intravenous injection in the urethra of rats after trauma by vaginal distention and compare them with controls and traumatized rats without treatment in regards to: (1) mRNA expression of collagens, vascular endothelial growth factor A (VEGF), nerve growth factor (NGF), Ki67 cell proliferation marker, and the expression of genes related to smooth and striated muscle apparatus; (2) expression of smooth and striated muscle proteins.

**Methods:** We investigated the urethras of three groups of rats: control, animals subjected to a 12-h intermittent vaginal distention only (VD) and that received MDSC therapy (VD+MDSC). MDSC were obtained from mutant rats expressing green fluorescent protein (GFP), and further cultivated in vitro. MDSC were injected into the tail vein of the rats at day 3 after VD and the urethras were analyzed at day 28.

We used real-time RT-PCR methodology for gene expression profile: Skeletal muscle myosin heavy chain (Myh1), Smooth muscle myosin heavy chain (Myh11), Ki67, Collagen type I (COL1), Collagen type III (COL3), VEGF and NGF.

We used Immunohistochemistry for identification and quantification of Myh11 and Myh1 proteins. The image analysis software HistoQuant (3DHISTECH) was used to selected immunopositive areas and obtain the value of the area marked in relation to the total area of each urethra.

Kruskal-Wallis test (Dunn's post-test) and ANOVA test (Tukey's post-test) were used for statistical analysis, with  $p < 0.05$  for significance.

**Results:** At 4 weeks after VD, Ki-67, COL1 and COL3 genes expression were significantly upregulated in VD+MDSC group compared to controls ( $p = 0.01$ ,  $p = 0.008$ ,  $p = 0.03$ , respectively). In addition, Ki-67 and COL1 genes were overexpressed in VD+MDSC group compared to VD ( $p = 0.02$ ,  $p = 0.03$ , respectively) (Fig. 1).

On the other hand, NGF mRNA expression was significantly downregulated after VD+MDSC compared to VD group ( $p = 0.002$ ). VEGF gene expression was not different among the groups (Fig. 1).

Myh11 and Myh1 genes were overexpressed in VD group in relation to control ( $p = 0.03$  and  $p = 0.04$ , respectively) with no